ORAL ARGUMENT SCHEDULED FOR APRIL 23, 2019

No. 18-5312

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN CLINICAL LABORATORY ASSOCIATION,

Plaintiff-Appellant,

v.

ALEX M. AZAR, II,
Secretary, United States Department
of Health and Human Services,

Defendant-Appellee.

Appeal from the United States District Court for the District of Columbia, No. 1:17-cv-02645, Hon. Amy Berman Jackson

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REPLY BRIEF OF APPELLANT AMERICAN CLINICAL LABORATORY ASSOCIATION

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March 18, 2018

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with Circuit Rule 28(a)(1) of the Rules of this Court, the undersigned, counsel of record for American Clinical Laboratory Association, certifies as follows:

A. Parties, Intervenors, *Amici*

1. Parties Before the District Court

The following is a list of all parties, intervenors, and participants who appeared before the United States District Court for the District of Columbia in the underlying proceedings:

Plaintiff, American Clinical Laboratory Association

Defendant, Alex M. Azar, II, Secretary of the United States Department of Health and Human Services

The following is a list of *amici* who appeared before the district court:

National Association for the Support of Long Term Care

Advanced Medical Technology Association

American Association of Bioanalysts

College of American Pathologists

2. Parties Before the Court

The following is a list of all parties, intervenors, and *amici* who have appeared in this Court:

Appellant, plaintiff below, American Clinical Laboratory Association

Appellee, defendant below, Alex M. Azar, II, Secretary of the United States Department of Health and Human Services

American Association of Bioanalysts as *Amicus Curiae* in support of Appellant American Clinical Laboratory Association

The College of American Pathologists as *Amicus Curiae* in support of Appellant American Clinical Laboratory Association

The Advanced Medical Technology Association as *Amicus Curiae* in support of Appellant American Clinical Laboratory Association

The National Association for the Support of Long Term Care as *Amicus Curiae* in support of Appellant American Clinical Laboratory Association

B. Rulings Under Review

The rulings under review are:

American Clinical Laboratory Association v. Azar, Memorandum Opinion, ECF Docket No. 47, No. 1:17-cv-02645-ABJ, --- F. Supp. 3d --- (D.D.C. Sept. 21, 2018) (The Honorable Amy Berman Jackson); and

American Clinical Laboratory Association v. Azar, Order, ECF Docket No. 46, No. 1:17-cv-02645-ABJ (D.D.C. Sept. 21,

2018) (The Honorable Amy Berman Jackson). No official reporter citation exists.

C. Related Cases

This case has not previously been before this Court or any other court. Counsel are not aware of any related cases pending in this Court or any other court.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

GLOSSARY

ACLA	American Clinical Laboratory Association
CMS	The Centers for Medicare & Medicaid Services
HHS	United States Department of Health and Human Services
NPI	National Provider Identifier
OIG	Office of Inspector General
PAMA	The Protecting Access to Medicare Act
Secretary	Secretary, United States Department of Health and Human Services

STATUTES AND REGULATIONS

The relevant statutory and regulatory provisions are contained in the addenda bound with ACLA's opening brief and the Secretary's response brief.

SUMMARY OF ARGUMENT

The Secretary's attempt to defend his final rule is unconvincing. Failing to address many of ACLA's arguments, he has not carried his burden to show that the jurisdictional bar applies. Nor has he advanced any credible defense on the merits.

1. The Secretary cannot dispute that the Protecting Access to Medicare Act ("PAMA") directs him to take two separate and formally distinct actions — *first*, engage in legislative rulemaking to promulgate a rule "establish[ing] . . . parameters for" collecting confidential market data from laboratories, *see* 42 U.S.C. § 1395m-1(a)(12), and, *second*, through a separate administrative process use the data to establish payment amounts for laboratory tests, *see id.* § 1395m-1(b)(1). Nor can he dispute that the statute's jurisdictional bar applies only to "the establishment of payment amounts." *Id.* § 1395m-1(h)(1). He points to no statutory text that expressly prohibits review of his final rule, which imposes new substantive data-reporting obligations on laboratories and does not itself establish payment amounts.

The Secretary also cannot deny that Congress directed him to undertake notice-and-comment rulemaking when setting the parameters

for collecting data, thereby requiring the Secretary to develop an administrative record that would be unnecessary if Congress intended to bar judicial review. Nor does he meaningfully address the grave constitutional concerns that would arise if, as he suggests, the Secretary were exempt from judicial review when promulgating and enforcing legislative rules that regulate primary conduct. Judicial oversight is essential to protecting private rights and ensuring that the Secretary acts within the bounds of his delegated authority.

In short, PAMA is "reasonably susceptible" to an interpretation that Congress did not intend to bar judicial review of the Secretary's final rule. *Kucana v. Holder*, 558 U.S. 233, 251 (2010); *El Paso Nat. Gas Co. v. United States*, 632 F.3d 1272, 1276 (D.C. Cir. 2011). The Secretary nonetheless urges the Court to adopt an expansive reading of the statutory bar. According to the Secretary, the bar should apply not only to the administrative act he takes to establish payment amounts but also to any other act he takes that "feeds" into the payment calculation. Gov't Br. 19. But that approach violates the bedrock rule that jurisdictional bars must be interpreted narrowly. It is not enough for the Secretary to

argue that his preferred interpretation is plausible; he must show that it is the only permissible reading. He has not met that heavy burden.

The Secretary also tries to find shelter in this Court's decisions in *Florida Health Sciences* and *Mercy Hospital*. But he fails to acknowledge the myriad ways in which those cases are distinguishable. In both cases the Court refused to dissect a unitary agency decision into its "inextricably intertwined" component parts. *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1067 (D.C. Cir. 2018); *Fla. Health Sci. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 519 (D.C. Cir. 2016). Here, in the contrast, the two separate actions taken by the Secretary, while connected, are not *inextricably* intertwined. The act of promulgating a legislative rule requiring private parties to report confidential data does not itself establish payment amounts. In fact, the Secretary did not act to establish final payment amounts until 17 months after he promulgated his final rule. *See* Gov't Br. 14–15; Office of Inspector General ("OIG"), Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies to Ensure Data Quality at App. B (July 2018), *available at* https://oig.hhs.gov/oei/reports/oei-09-17-00050.pdf.

2. In any event, regardless of the scope of any jurisdictional bar, the Court should reverse because the Secretary's rule and the later payment amounts he established are *ultra vires*. The Secretary attempts to recast ACLA's challenge as complaining only that his rule is over-inclusive and therefore arbitrary and capricious. In fact, his rule patently exceeds his authority and disregards an unambiguous statutory directive. Instead of collecting data from all applicable laboratories, the final rule rewrites the statute to exempt virtually all hospital laboratories from the mandatory data-reporting obligations that Congress imposed. The result is contrary to Congress's intent that the data collected by the Secretary, and the rates later established using that data, would reflect the private payor market as a whole.

The Secretary's *ultra vires* rule should be struck down, the *ultra vires* payment rates should be vacated, and the Secretary should be required to do the job that Congress intended.

ARGUMENT

I. This Case Does Not Fall Within Any Jurisdictional Bar.

The Secretary argues that PAMA's jurisdictional bar should be interpreted broadly. That argument cannot be reconciled with the statute's text and structure. It also violates the principle that jurisdictional bars must be interpreted narrowly.

A. PAMA's Text and Structure Show That Congress Did Not Intend to Bar Judicial Review.

As ACLA's opening brief explains, PAMA's text and structure show that Congress directed the Secretary to undertake two separate and logically distinct actions, addressed the Secretary's obligations to perform those actions in different statutory provisions, and barred judicial review of only one of them. ACLA Br. 13–17, 38–41. Congress precluded judicial review of only "the establishment of payment amounts." 42 U.S.C. § 1395m-1(h)(1). It did not bar review of the Secretary's final regulations establishing the parameters for collecting confidential data from laboratories. *Compare id.* § 1395m-1(a)(1)–(12) (directing the Secretary to promulgate regulations "establish[ing] . . . parameters for data collection"), *with id.* § 1395m-1(b)–(i) (directing the Secretary to "establish[] payment amounts").

1. The Secretary argues that the statutory bar should be interpreted broadly to encompass not only his establishment of payment amounts but also any "steps taken to reach the ultimate payment amounts," including the separate act of promulgating regulations that impose new data-reporting requirements on laboratories. Gov't Br. 18; *see also id.* at 23, 34. That approach contravenes the strong presumption that Congress intends judicial review of administrative action "even where . . . the statute expressly prohibits judicial review." *El Paso*, 632 F.3d at 1276; ACLA Br. 44–46.

It is not enough for the Secretary to propose a plausible interpretation of the statute. His "heavy burden" is to show that his preferred reading is the only permissible one. *See Mach Mining, LCC v. EEOC*, 135 S. Ct. 1645, 1651 (2015). Because a narrower construction is available, the Secretary has not met his burden. He has not, in short, demonstrated with "clear and convincing evidence" that Congress wanted him to police his own conduct. *Id.*; *see also SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

2. Attempting to defend his broad reading of the statutory bar, the Secretary advances two textual arguments. Neither has merit.

The Secretary first embraces the district court's attempt to draw meaning from the fact that Congress addressed the Secretary's obligation to promulgate data-collection regulations in the same general section of the statute as his separate obligation to establish payment amounts. Gov't Br. 24, 31–32. For reasons explained in ACLA's opening brief, that approach fails to account for the statute's precise language and structure. ACLA Br. 41–44.

The statute addresses the Secretary's obligation to promulgate regulations establishing the "parameters for data collection" in subsection (a). 42 U.S.C. § 1395m-1(a)(12). That subsection directs the Secretary to undertake notice-and-comment rulemaking to establish the "parameters for data collection," *id.*, sets out penalties for non-compliance, *id.* § 1395m-1(a)(9), and mandates that the Secretary protect the laboratories' confidential data, *id.* § 1395m-1(a)(10). In contrast, the remaining subsections address the Secretary's separate obligation to establish payment amounts for different types of diagnostic tests. In each subsection, the statute refers to the "establishment of payment amounts" and provides specific instructions on how the Secretary must fulfill his obligation to calculate the amount that Medicare will pay for certain

types of tests. *See id.* § 1395m-1(b)(1)(A) (requiring payment amounts for clinical diagnostic tests to be "equal to the weighted median determined for the test"); *id.* § 1395m-1(c) (requiring payment amounts for new tests that are not advanced diagnostic laboratory tests to be determined using cross-walking or gapfilling processes); *id.* § 1395m-1(d)(1)(A) (requiring payment amounts for advanced diagnostic tests to "be based on the actual list charge for the laboratory test").

Congress barred judicial review of the establishment of payment amounts but did not bar review of the Secretary's final regulations establishing the parameters for data collection. The inclusion of "particular language in one section of a statute" and the "omi[ssion of] it in another section" is presumed to be intentional. *Dean v. United States*, 556 U.S. 568, 573 (2009); *cf. Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1130 (D.C. Cir. 2017) (in a statutory paragraph that described different processes, Congress used specific cross-references to specify which process it referred to in each provision; the omission or inclusion of specific cross-references was intentional). The Secretary cannot rewrite the jurisdictional bar on "establishment of payment amounts" to mean "establishment of the parameters for data collection" merely because the

separate obligations appear in the same section of the statute. *Dean*, 556 U.S. at 572.

The Secretary also emphasizes that PAMA contains "specific oversight mechanisms," Gov't Br. 30–31, but the provisions he cites show only that Congress distinguished between different types of agency action — and calibrated the level of oversight to the type of action.

When Congress enacted PAMA, it wanted to ensure that Medicare payment rates more closely reflect the private market. Allowing for judicial review of the Secretary's final rule is consistent with that objective. Congress must have recognized that when the Secretary is engaged in legislative rulemaking, judicial oversight helps to ensure that his rule complies with Congress's commands. *See Sackett v. EPA*, 566 U.S. 120, 130–31 (2012) (rejecting agency position that would "enable the strong-arming of regulated parties into 'voluntary compliance' without the opportunity for judicial review"). Judicial review in this context falls within the judiciary's traditional and core expertise. ACLA Br. 50–51. Similarly, to put itself in a position to make legislative adjustments, Congress directed the Government Accountability Office to study "whether the information reported by laboratories and the new payment

rates for laboratory tests . . . accurately reflect market prices." PAMA, Pub. L. No. 113-93, § 216(c)(1)(A), 128 Stat. 1040, 1061 (2014). Congress thus intended that there would be both a judicial and a legislative check to ensure that the data collected by the Secretary reflects the private payor market.

In contrast, Congress recognized that when the Secretary is establishing payment amounts, judicial review is less important. Setting payment rates is a technical, regulatory function that falls outside the judiciary's core expertise. Allowing judges to review every change in rates could clog the courts and interfere with the agency's rate-setting process. Moreover, as long as the agency's final regulations establishing the parameters for collecting data are consistent with statutory requirements, the risk of administrative error when the Secretary later establishes payment amounts is far less.

Congress therefore barred judicial review of the Secretary's establishment of payment amounts and instead directed the Secretary to consult with experts and to seek public input. For example, the statute requires the Secretary to consult with an expert advisory panel when establishing rates for *new* clinical diagnostic tests. 42 U.S.C. § 1395m-

1(f)(1)(A); *see, e.g.*, Centers for Medicare & Medicaid Services ("CMS"), Advisory Panel on Clinical Diagnostic Laboratory Tests, Voting Results and Recommendations (Sept. 25, 2017) (recommending specific payment calculations for new tests, including whether to use cross-walking or gapfilling). The statute also mandates that the agency publicly release data analysis "of the top 25 laboratory tests by expenditures," PAMA, § 216(c)(2)(A), 128 Stat. at 1061, and convene annual meetings to receive "comments and recommendations" on "the establishment of payment amounts," 42 U.S.C. § 1395m-1(f)(3).

3. The Secretary next asserts that establishing payment amounts "*naturally involves* identifying which laboratories must report data, specifying what private-sector data is required, setting the timeframe for when reporting data should occur, and finally calculating the payment rate from that data." Gov't Br. 23 (emphasis added). That is obviously incorrect. The Secretary often establishes payment amounts using data that is already available to him and, in those circumstances, selecting what data to use could well be part and parcel of the same administrative act of deciding what the payment amounts should be. *See Fla. Health*, 830 F.3d at 518–21.

Here, in contrast, Congress directed the Secretary to undertake notice-and-comment rulemaking to promulgate regulations imposing new substantive data-reporting obligations on laboratories. There is nothing about *that* rulemaking process that is "naturally involved" in carrying out the separate administrative function of establishing payment amounts.

The Secretary also suggests that because establishing payment amounts involves a "standard" mathematical calculation, a broad reading of the jurisdictional bar is warranted. Gov't Br. 32–33. According to the Secretary, "[i]t is implausible that Congress would single out basic math as unreviewable, while permitting review of every discretionary step that preceded that math." *Id.* at 33. But the Secretary's statutory obligation to promulgate regulations imposing new data-reporting obligations on "applicable laboratories" is not a "discretionary" act. Moreover, the Secretary's separate administrative act establishing payment amounts includes more than the Secretary's "math homework." It also involves other types of analysis, including the Secretary's analysis of new clinical diagnostic laboratory tests and explanation of the payment rates for those tests. 42 U.S.C. § 1395m-1(c).

Nor are the mathematical calculations as simple as the Secretary suggests. The Secretary must array data from *thousands* of laboratories, ACLA Br. 22, and then apply a formula to calculate a weighted median for each type of clinical diagnostic laboratory test. 42 U.S.C. § 1395m-1(b)(1)–(5). For new tests, establishing payment amounts requires taking into account a variety of criteria and considering recommendations provided by an expert panel. *Id.* § 1395m-1(c)(1)–(3).

It is unsurprising that Congress would preclude judicial review of the administrative functions performed when the Secretary establishes payment amounts (including the Secretary's mathematical calculations). When the Secretary sets payment amounts, he is only regulating secondary conduct by determining what amounts the government is willing to pay for services provided. It is equally unsurprising, however, that Congress did not intend to preclude judicial review of the Secretary's legislative regulations imposing new data-reporting obligations on laboratories. Unlike the Secretary's payment calculations, the Secretary's final rule "trenches on substantial private rights and interests." *Mendoza v. Perez*, 754 F.3d 1002, 1023 (D.C. Cir. 2014). Because it regulates laboratories' primary conduct, judicial review is

essential to ensuring that the Secretary acts within the bounds of his delegated authority and consistent with his statutory mandate. ACLA Br. 47–50.

Permitting judicial review of the Secretary's final rule imposing new substantive obligations on laboratories, while precluding review of the Secretary's decisions setting payment amounts, promotes the "certainty and stability" that the Secretary says is important. *Cf. Rodriguez v. United States*, 480 U.S. 522, 526 (1987) ("[I]t frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law."). It does so by ensuring that the Secretary complies with his statutory obligations when promulgating a new legislative rule. If the Secretary's final rule does not comply with the statutory requirements, courts are available to strike down the invalid rule and vacate any payment calculations that are infected by the statutory violation. *Cf. W.C. v. Bowen*, 807 F.2d 1502, 1505 (9th Cir. 1987) ("Agency action taken under a void rule has no legal effect."). In contrast, if the final rule survives judicial review, the jurisdictional bar prevents "disruption to the

Secretary's administration of the" Medicare program when the Secretary sets particular rates. Gov't Br. 29.

4. The Secretary does not raise any direct challenge to ACLA's standing, effectively abandoning the meritless arguments he advanced in the district court. *See* Gov't Br. 26 n.5 (suggesting that the quantum of any injury is "uncertain," but not disputing that ACLA's members are the direct objects of regulation). Nonetheless, he asserts that ACLA's standing theory is inconsistent with its interpretation of the statute. *Id.* at 25–26. That argument is also meritless.

ACLA has standing because its members are directly regulated by, and subject to, the substantive requirements of the Secretary's final rule. ACLA Br. 33–34. ACLA and its members have a right to have the statute applied consistently with Congress's directives. Moreover, ACLA and its members have been harmed by the Secretary's rule because it requires them to undertake the "difficult, resource-intensive, and burdensome" task of reporting data while unlawfully exempting hospital outreach laboratories — their direct competitors — from those burdens. *Id.* at 34–35. Requiring hospital outreach laboratories that meet the definition of applicable laboratory to report data, as Congress intended, would impose

"the same burden of identifying and reporting accurate applicable information" on all applicable laboratories. 83 Fed. Reg. 59,452, 59,674 (Nov. 23, 2018).

Nor is ACLA's statutory argument "incompatible" with the reality that ACLA's members have suffered and will continue to suffer harm from the invalid payment amounts. Gov't Br. 25–26. The fact that harm from invalid payment amounts can be traced back to the Secretary's earlier establishment of data collection parameters for standing purposes does not mean that the two agency actions are one and the same as a matter of statutory interpretation.

ACLA thus acknowledges that there is a connection between the Secretary's final rule and his later establishment of payment amounts. ACLA Br. 33–36; *see Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992); *Sierra Club v. EPA*, 292 F.3d 895, 899–900 (D.C. Cir. 2002). If the Secretary's final rule is invalid because it exceeds the Secretary's authority and violates the statute, then the payment amounts established by the Secretary are necessarily *ultra vires* because they are infected by the invalid rule and rely on data obtained through an unlawful process.

This connection between the final rule and the established payment amounts is sufficient for standing purposes, but as discussed in more detail below, it does not mean that the two acts are "inextricably intertwined" for purposes of the jurisdictional bar. The burden on ACLA to demonstrate standing is simply not the same as the burden on the Secretary to demonstrate that his final rule is exempt from judicial review. *Compare Am. Library Ass'n v. FCC*, 401 F.3d 489, 493 (D.C. Cir. 2005) ("to establish injury in fact, petitioners must show that there is a substantial probability that the [agency action] will harm the concrete and particularized interests of at least one of their members"), *with Mach Mining*, 135 S. Ct. at 1651 ("the agency bears a heavy burden in attempting to show that Congress prohibited all judicial review of the agency's compliance with a legislative mandate" (alterations and internal quotation marks omitted)), *and Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1043 (D.C. Cir. 1979) (agency failed to show "anything approaching a clear and convincing legislative intent to negate review").

B. The Nature of the Secretary's Action Confirms That Congress Did Not Intend to Bar Judicial Review.

The Secretary does not substantively address ACLA's arguments that the presumption in favor of judicial review is especially strong in

this case because of "the nature of the administrative action involved." *Dart v. United States*, 848 F.2d 217, 224–26 (D.C. Cir. 1988) (quoting *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984)); ACLA Br. 46–56. The long-standing distinction between coercive actions an agency takes to regulate primary conduct (imposing new constraints or obligations on private parties) and administrative acts that an agency takes that affect only secondary conduct (establishing payment rates) is not a meaningless "abstract[ion]." Gov't Br. 20.

The Secretary echoes the district court's suggestion that the final rule does not regulate primary conduct merely because it does not "regulate the work of laboratories." Gov't Br. 35. But he cites no authority for that position and he should be embarrassed to advance it. The distinction between agency action that regulates primary conduct and action that affects only secondary conduct has nothing to do with whether "*with respect to testing*, each laboratory is 'free to conduct its business as it sees fit.'" Gov't Br. 36 (emphasis added). Instead, the distinction is grounded in separation-of-powers principles. ACLA Br. 47.

When an administrative agency imposes new substantive obligations on private parties backed by the coercive power of the state,

the agency is regulating primary conduct. In that context, judicial oversight and certain procedures, such as notice-and-comment rulemaking, are ordinarily necessary to ensure that the agency does not overstep the bounds of its delegated authority and trample on private rights. ACLA Br. 50–51; *cf. Mistretta v. United States*, 488 U.S. 361, 396 (1989) (upholding delegation where Congress did not transfer authority to make rules that "bind or regulate the primary conduct of the public"). Exempting that type of agency action from judicial review would require an especially clear statement of Congressional intent and, depending on the circumstances, could raise significant constitutional concerns. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."); ACLA Br. 54–55.

By contrast, judicial review and procedural safeguards are not as critical when an agency is performing a purely administrative function, such as establishing the amount of money the government will pay for

services rendered. ACLA Br. 49. In those situations, the agency's actions affect only private parties' secondary conduct because they do not require regulated parties "to engage in, or to refrain from, [certain] conduct." *Texas v. United States*, 523 U.S. 296, 301 (1998); *Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 164–65 (1967). A party may not like the payment rates the government is prepared to pay, but the rates themselves are not a coercive exercise of government power.

These bedrock principles reinforce why Congress separated the Secretary's obligation to promulgate regulations imposing new data-reporting obligations from his later administrative act establishing payment amounts. *See Hall v. United States*, 566 U.S. 506, 516 (2012) (courts "assume that Congress is aware of existing law when it passes legislation"). The same logic undergirds the Court's decisions addressing when a case is ripe or when agency action is final. *Cf.* Gov't Br. 36–37 (claiming that these cases represent "distinct situations"). Judicial ripeness and finality doctrines identify when an agency action changes from being non-binding because it is tentative or preliminary to a "consummation of the agency's decisionmaking process" that determines

"rights or obligations" backed by the coercive power of the state. *See Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1137 (D.C. Cir. 2010).

Contrary to the Secretary's suggestions, it is also unsurprising that the Court has not had occasion to apply these distinctions in the context of a jurisdictional bar. Gov't Br. 36–37. None of the cases cited by the Secretary involved legislative rules that regulate parties' primary conduct. For example, the final rule in *Florida Health* did not impose a new obligation on regulated parties to report data; HHS already had the data. 830 F.3d at 517. Similarly, the only agency action at issue in *Texas Alliance for Home Care Services v. Sebelius* was the agency's "formulation and application" of standards for analyzing financial information voluntarily submitted with bids for contracts. 681 F.3d 402, 408–10 (D.C. Cir. 2012). Nor did these cases concern separate agency actions that are different in nature (legislative rulemaking versus an exercise of administrative discretion) and subject to different procedural requirements (notice-and-comment rulemaking versus a mere notice).

The Secretary also misunderstands the constitutional concerns raised by his broad interpretation. ACLA Br. 54–56. The Secretary emphasizes that civil penalties are generally subject to review in

administrative proceedings and on appeal, *see* Gov't Br. 37, but that misses the point. ACLA is not disputing that a laboratory would be able to raise fact-specific defenses in an enforcement action — for example, that it properly reported data or was exempt from reporting. ACLA's argument is more fundamental: Under the Secretary's expansive interpretation of the statutory bar, a party on the wrong end of an enforcement action would be barred from arguing that the penalties should not be imposed because the Secretary's rule is contrary to the statute or in excess of his lawful authority.

That would be a uniquely sweeping delegation of agency authority that would raise serious separation-of-powers concerns. ACLA Br. 54–55 (citing *Sackett*, 566 U.S. at 129–31). There is no reason to conclude that Congress intended such an extraordinary result. The Secretary has not carried his heavy burden to provide clear and convincing evidence that Congress intended to eliminate judicial oversight.

C. *Florida Health* Undermines the Secretary's Position.

Unable to show that PAMA is not "reasonably susceptible" to an interpretation that permits judicial review, *Kucana*, 558 U.S. at 251, the

Secretary retreats to *Florida Health*'s "inextricably intertwined" test. Gov't Br. 22–23, 26–28. But the Secretary misapplies that decision.

While *Florida Health* rejected the categorical contention that the inputs to a payment calculation are necessarily separate from the payment calculation itself, it did not embrace the Secretary's equally categorical position that any agency act that results in an input to a payment calculation is necessarily subject to the jurisdictional bar. Nor did it upend the usual rule that courts review final "agency actions" and not the "steps" that an agency takes to further some ultimate statutory objective. *See* 5 U.S.C. §§ 702, 704. Contrary to the Secretary's position, *Florida Health* applies only when a party tries to circumvent a jurisdictional bar by dividing a unitary agency action into its inextricably intertwined parts. It does not displace the baseline requirement that jurisdictional bars must be interpreted narrowly.

The appropriate analysis requires first identifying the relevant final agency action subject to review and then applying traditional tools of statutory construction to determine Congress's intent with every presumption made in favor of judicial review. *See Fla. Health*, 830 F.3d at 519, 521. If the challenged action does not fall within the jurisdictional

bar interpreted narrowly — in this case, if it is possible to say that the final rule itself is not an establishment of rates — the *Florida Health* test is irrelevant. If, in contrast, the challenged action does fall within the bar narrowly interpreted, the Court should then apply the *Florida Health* test to determine whether either (1) the action can be divided into its component parts in light of the principle that jurisdictional bars must be interpreted narrowly or (2) the parts are so inextricably intertwined that dividing the action for purposes of judicial review would defeat Congress's intent. *Id.* at 521 (holding that the Secretary's selection of pre-existing data "fits squarely within" the jurisdictional bar, even "viewing the bar here narrowly," and that "[t]he data and the estimate are so closely intertwined that [the Court] cannot review either"); *see also Mercy Hosp.*, 891 F.3d at 1067 (holding first that "as a textual . . . matter," the Secretary's rate adjustment fell within the statutory bar and second that "practical[ly]" the adjustment formula and final rate could not be separated).

Here, for reasons explained above, the agency action subject to judicial review — the Secretary's final rule — does not fall within the statutory bar. It does not itself establish payment amounts. It results

from a separate agency action (promulgating a legislative rule) that is fundamentally different in quality and kind from the administrative act Congress included within the jurisdictional bar (establishing payment amounts). The statute's text treats the different acts separately, and there are strong policy reasons, grounded in separation-of-powers principles, not to sweep the final rule into the ambit of the jurisdictional bar. In short, the *Florida Health* test does not apply.

Even if the test did apply, however, the result would be the same because the Secretary's final rule is not "inextricably intertwined" with his later establishment of payment amounts. Unlike the discretionary choice of what vintage data to use in *Florida Health* and the rate adjustment formula applied in *Mercy Hospital*, the Secretary promulgated a legally binding rule that imposed substantive obligations on laboratories to report confidential market data. That rule is separate from the Secretary's later action of using the collected data to establish payment amounts. ACLA Br. 59–60. It also can be reviewed based solely on whether the Secretary has complied with statutory requirements; no one is asking the Court to array the data itself and re-do the Secretary's math. Accordingly, permitting a challenge to the final rule would not

"eviscerate the bar on judicial review." *Fla. Health*, 830 F.3d at 519. Nor would it threaten the stability of the Medicare payment system. Gov't Br. 29.

Permitting judicial review of the Secretary's first substantive action (imposing data-reporting requirements) while precluding review of the Secretary's later ministerial action (using the collected data to establish the rates) strikes the right balance. It ensures that the Secretary's regulation of parties' primary conduct is subject to a judicial check, while preventing courts from getting caught up "in 'the technical and complex determinations'" of rate calculations. *Traynor v. Turnage*, 485 U.S. 535, 544 (1988) (quoting *Johnson v. Robison*, 415 U.S. 361, 370 (1974)); ACLA Br. 53, 61. As long as a judicial check exists to ensure that the Secretary complies with statutory requirements when establishing the parameters for data collection, Congress can be confident that the payment amounts, whenever and however they may be later established, will be consistent with the statute's overarching objective of having the Medicare payment rates approximate the commercial market.

The Secretary's interpretation disregards these distinctions. According to the Secretary, the agency's regulation is "inextricably

intertwined" with its later "payment calculation" because the two actions are related. Gov't Br. 28; *but cf. The American Heritage Dictionary* (5th ed. 2012) (defining "inextricable" as "(a) [s]o intricate or entangled as to make escape impossible[;] (b) [d]ifficult or impossible to disentangle or untie"). Under the Secretary's position, it is not possible for Congress to bar review of an agency's technical rate calculations without also precluding review of separate agency actions that impose time-consuming and expensive obligations on regulated parties. But without judicial review of the final rule, the Secretary can impose his will on laboratories in a way that violates Congress's intent and results in payment rates that are not representative of the market as Congress intended. Neither *Florida Health* nor the cases applying it go so far.

II. The Secretary's Final Rule Is Ultra Vires And In Excess of His Statutory Authority.

The Supreme Court has made clear that "[b]oth [agencies'] power to act and how they are to act is authoritatively prescribed by Congress." *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 297 (2013); ACLA Br. 61–63. Accordingly, agencies act *ultra vires* "when they act beyond their jurisdiction" *and* "when they act improperly." *City of Arlington*, 569 U.S.

at 291. Judicial review is available whenever an agency has "act[ed] outside its statutory limits." *SAS Inst.*, 138 S. Ct. at 1359.

The Secretary's narrow conception of the *ultra vires* exception is at odds with this controlling precedent. In the Secretary's view, *ultra vires* review is available only when an agency acts "beyond the scope of [its] lawful authority," Gov't Br. 21, such as "where Congress has authorized an agency to regulate one matter but the agency regulates a different matter altogether." *Id.* at 43; *see also id.* at 40. But *City of Arlington* rejected that position. 569 U.S. at 291–301. As the Supreme Court explained, for purposes of determining whether an agency has acted *ultra vires*, "there is *no difference* . . . between an agency's exceeding the scope of its authority (its 'jurisdiction') and its exceeding authorized application of authority that it unquestionably has." *Id.* at 299; *see also id.* at 297. The "question in every case is, simply, whether the statutory text forecloses the agency's assertion of authority." *Id.* at 301. If so, the agency's action is *ultra vires*. *Id.* at 291.

Here, the Secretary's rule "go[es] beyond what Congress has permitted it to do" because it rewrites the statute to exempt hospital laboratories from the mandatory data-reporting obligations that

Congress unambiguously imposed. *Id.* at 298. It is undisputed that Congress directed the Secretary to collect data from any laboratory that receives a majority of its Medicare revenues from the Clinical Laboratory Fee Schedule and the Physician Fee Schedule. Gov't Br. 5; 83 Fed. Reg. at 59,675 (acknowledging that the Secretary cannot "exclude[] laboratories that meet the majority of Medicare revenues threshold from potentially qualifying as an applicable laboratory"). It is also undisputed that Congress required the Secretary to determine whether a laboratory is "applicable" and thus must report data by comparing the laboratory's revenues from the relevant fee schedules against its overall total Medicare revenues. Gov't Br. 5–6.

Notwithstanding these instructions, the Secretary's final rule eliminates PAMA's majority-of-the-revenues requirement when applied to hospital laboratories. ACLA Br. 64–66. Instead of comparing the *laboratory*'s total revenues from the relevant fee schedules with the *laboratory*'s total Medicare revenues, as Congress directed, the final rule compares the laboratory's total revenues from the relevant fee schedules with the total Medicare revenues of *any* entity with a National Provider Identifier ("NPI"), of which the laboratory is often only one component.

Because nearly all hospital laboratories bill under their hospitals' general NPIs, the final rule takes into account massive amounts of Medicare revenues received by the hospitals as a whole. ACLA Br. 19, 65–66. As a result, the final rule exempts hospital laboratories from data-reporting requirements, even if a majority of the hospital laboratory's Medicare revenues are from the relevant fee schedules. 83 Fed. Reg. at 59,675 (acknowledging that "hospital outreach laboratories without unique NPIs furnish clinical laboratory tests paid under the [relevant fee schedules]" but the 2016 final rule excluded such laboratories).

Unable to dispute that his final rule excludes laboratories that "meet the majority of Medicare revenues threshold," 83 Fed. Reg. at 59,675, the Secretary argues that the rule is not *ultra vires* because it applies the majority-of-the-revenues requirement to the few hospital outreach laboratories that do have separate NPIs. Gov't Br. 42–43; *see also id.* at 41 n.7 (noting that "hospital laboratories *may* 'obtain[] a unique [National Provider Identifier] (separate from the hospital)'" (emphasis added)). But the Secretary cannot excuse his failure to follow

Congress's clear direction in most instances by saying that he complied with the statute in barely a few.

Nor can the Secretary save his final rule by arguing that it was theoretically possible for the rule to comply with the statute, if all hospital laboratories had voluntarily obtained their own NPIs. Gov't Br. 42. There is no requirement that a hospital laboratory have its own NPI to bill the Medicare program. ACLA Br. 19; JA619. As commenters repeatedly pointed out during the rulemaking, and the Secretary recently acknowledged, it is almost always the case that a hospital laboratory will bill for services under the relevant fee schedules using the NPI of the hospital as a whole. JA619, JA089 ¶ 32; *see also* 83 Fed. Reg. at 59,675. Because obtaining a separate NPI is voluntary, the Secretary's final rule effectively makes PAMA's reporting obligations optional for hospital laboratories. But as the Secretary conceded in his most recent rulemaking, PAMA does not permit the Secretary to exempt these laboratories "from reporting the applicable data merely due to their shared use of a billing entity with a hospital." 83 Fed. Reg. at 59,675.

The Secretary's position appears to be that he is not required to comply with PAMA's specific, unambiguous provisions because it is not

always a simple task to determine the revenues attributable to a hospital laboratory. But even if the statutory task is challenging, the Secretary is not free to "throw up [his] hands" and rewrite the statutory requirements. *Cobell v. Salazar*, 573 F.3d 808, 813 (D.C. Cir. 2009). Nor is it enough for the Secretary to insist that he tried his best to comply. As demonstrated by ACLA's proposed method in its comments and the Secretary's new approach outlined in his recent rulemaking, there are several ways to identify and measure a laboratory's total Medicare revenues without taking into account unrelated revenues. *Cf.* Gov't Br. 40. The Secretary could have picked a method that identified a laboratory's total Medicare revenues and compared it against the revenue that laboratory received from the relevant fee schedules, as required by the statute. But that is not what the Secretary did. Instead, the Secretary chose a proxy that rewrote the statute by replacing the word "laboratory" with the words "any entity with an NPI that has at least one component that is a laboratory." ACLA Br. 69–70. That rewrite is clearly foreclosed by the statutory text and is therefore *ultra vires*. *City of Arlington*, 569 U.S. at 301; *see also SAS Inst.*, 138 S. Ct. at 1359.

By excluding nearly all hospital outreach laboratories from the data-reporting requirements, the Secretary excluded data from an entire segment of the market. ACLA Br. 22–23. Forced to concede that the statute does not permit this exclusion, 83 Fed. Reg. at 59,675, the Secretary tries to argue that his statutory violation does not matter. Gov't Br. 44. But the Secretary has no answer for the fact that a mere 1 percent of the reported laboratory test volume came from hospital laboratories, even though hospital laboratories received 26 percent of the Clinical Laboratory Fee Schedule payments in 2016. ACLA Br. 66.

This data gap was a direct result of the Secretary's final rule and not, as the Secretary contends, other "one-time challenges." Gov't Br. 44. Contrary to the Secretary's suggestion, the statute's low expenditure threshold rate has nothing to do with the low percentage of outreach hospital laboratory reporting, because the final rule excluded hospital laboratories entirely, regardless of the amount of their expenditures. *Id.* (citing JA466). (The Secretary recognizes that the low expenditure threshold rate only reduced the number of physician office laboratories and independent laboratories required to report. JA466; Gov't Br. 44.) Likewise, the allegedly high rate of reporting from physician office

laboratories and independent laboratories does not compensate for the almost nonexistent rate of reporting from hospital outreach laboratories. Gov't Br. 44. The challenges faced by other laboratories required to report data are also irrelevant. *Id.*

In the end, the Secretary's statutory departures resulted in a data collection that did not include data from all "applicable laboratories," as required by Congress. Because the Secretary "act[ed] outside [his] statutory limits," *SAS Inst.*, 138 S. Ct. at 1359, his final rule and any data collection pursuant to that rule is *ultra vires*. *Id.*; *see also City of Arlington*, 569 U.S. at 291. Moreover, because the Secretary's 2017 establishment of payment rates are based on invalid data collected in violation of the statute, the rates themselves are also *ultra vires* and must be vacated.

CONCLUSION

The Court should reverse the district court's order dismissing ACLA's claims for lack of subject-matter jurisdiction.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the length limitations set forth in Federal Rule of Appellate Procedure 32(a)(7) because it contains 6,492 words, as counted by Microsoft Word, excluding the items that may be excluded.

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CERTIFICATE OF SERVICE

On March 18, 2019, I caused a copy of the foregoing document to be served electronically on all registered counsel through the Court's CM/ECF system.

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