ORAL ARGUMENT NOT YET SCHEDULED

No. 18-5312

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

Brief of Amicus Curiae American Association of Bioanalysts in Support of Plaintiff-Appellant, American Clinical Laboratory Association, Seeking Reversal

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

A. Parties, Intervenors, *Amici*

1. Parties Before the District Court

All parties, intervenors, and *amici* who appeared before the United States District Court for the District of Columbia in the underlying proceedings are listed in the Brief for American Clinical Laboratory Association.

2. Parties Before the Court

Except for an *amicus* being filed by American Association of Bioanalysts, all parties, intervenors and *amici* appearing in this court are listed in the Brief for American Clinical Laboratory Association.

B. Rulings Under Review

Reference to the rulings at issue appear in the Brief for American Clinical Laboratory Association.

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.

CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rules of Appellate Procedure 26.1 and D.C. Circuit Rules 28 and 26.1, *amicus curiae* American Association of Bioanalysts ("AAB") certifies that AAB has no corporate parent and, since it is organized as a non-profit, tax-exempt organization, no publicly held corporation owns 10% or more of its stock.

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GLOSSARY

ACLA	American Clinical Laboratory Association
AAB	American Association of Bioanalysts
CMS	The Centers for Medicare & Medicaid Services
Final Rule	81 Fed. Reg. 41,036 (June 23, 2016)
HHS	United State Department of Health and Human Services
NPI	National Provider Identifier
PAMA	The Protecting Access to Medicare Act
Secretary	Secretary, United State Department of Health and Human Services

IDENTITY AND INTEREST OF THE *AMICUS CURIAE*[1]

The American Association of Bioanalysts ("AAB") submits this Brief in support of the appeal by Plaintiff-Appellant, American Clinical Laboratory Association. AAB is a not-for-profit corporation organized in California, with a principal office in St. Louis, Missouri, that has represented the clinical laboratory community for 62 years. AAB is the principal trade association for community and regional clinical laboratories nationwide. AAB has a strong and demonstrable interest in this case because its members have been and will continue to be negatively affected by the Secretary's Final Rule, 81 Fed. Reg. 41,036 (June 23, 2016) (codified at 42 C.F.R. pt. 414.500 *et. seq*.) that adopts a definition of "applicable laboratory" that is inconsistent with Section 216 of the Protecting Access to Medicare Act ("PAMA") and defeats the purpose of Congress in directing the Secretary to collect data regarding rates paid to laboratories in all

[1] This brief was authored in whole by its general counsel, O'Connell & Aronowitz, P.C., and no party's counsel authored this brief in whole or in part. No party's counsel contributed money that was intended to fund preparing or submitting this brief. No person, other than the amicus curiae and its members, contributed money that was intended to fund preparing or submitting this brief.

sectors of the commercial market. AAB's organizational interest in promoting the public's access to high quality laboratory services will also be harmed by the challenged definition of "applicable laboratory". AAB filed an amicus brief in support of Plaintiff in the District Court. The authority to file an amicus brief here is by consent of all parties.

AAB submits this amicus brief own its own, recognizing the Court's preference to have joint amicus briefs, for two principal reasons: (1) the work on this brief was done pro bono by AAB's general counsel; and (2) this short brief addresses just one point, that regardless of how intertwined the administrative decision to limit which laboratories would be applicable is with the establishment of payment amounts, that act of rejecting and rewriting the statutory definitions is an *ultra vires* act that is reviewable.

STATUTES AND REGULATIONS

All applicable statutes and regulatory provisions are contained in the Brief for American Clinical Laboratory Association.

ARGUMENT

We adopt all of the arguments made in the brief submitted by Plaintiff-Appellant, American Clinical Laboratory Association ("ACLA"). We write only to address the overly broad and incorrect application of the

"inextricably intertwined" test relied upon by the District Court. That test need not be reached, because Congress did not intend to bar challenges to the regulations adopted to define which laboratories were required to submit data, i.e., which were the "applicable laboratories." We write to argue that even if the definition adopted by the Secretary were inextricably intertwined with the establishment of payment amounts, which we do not agree with, that relationship would not shield the Secretary's *ultra vires* actions from challenge. The definition adopted by the Secretary is subject to judicial review because Congress granted no authority to the Secretary to redefine a term that Congress clearly and expressly defined in statute.

POINT I

The Challenged Aspect of the Final Rule is *Ultra Vires* and Reviewable by the Court

The District Court found that it could not review the Secretary's Final Rule re-defining "applicable laboratory" and, thereby which laboratories must report data, because the selection of that definition was "inextricably intertwined" with the agency's subsequent action of establishing payment amounts. JA445. The District Court's heavy reliance upon *Florida Health Sciences Center, Inc. v. Sec'y of Health and Human*

Servs., 830 F.3d 515, 521 (D.C. Cir. 2016), was, however, misplaced because the District Court failed to consider that the Secretary's challenged action was *ultra vires*. Citing to *Florida Health*, the District Court held that the applicability of a jurisdiction-stripping provision "turns on the relationship between the challenged decision and the agency action shielded from review, and that it 'could not review a decision that was 'indispensable' or 'integral' to, or 'inextricably intertwined' with, the unreviewable agency action.'" JA444 (citing *Florida Health*, 830 F.3d at 519).

It concluded, therefore, that

> which laboratories must report data is "indispensable" and "integral" to, and "inextricably intertwined" with, the agency action's calculation of payment amounts based on that data and "the establishment of payment amounts under" Section 216. Therefore, it is not subject to judicial review." JA445.

It is well-established, however, that an agency regulation is subject to review when the agency acted outside its scope of authority, despite jurisdiction-stripping language. *COMSTAT Corp. v. F.C.C.*, 114 F.3d 223 (D.C. Cir. 1997) (holding that the FCC's promulgation of regulations that added a new category of fees was outside its authority and reviewable despite the statutory language that prohibited review of "increases or

decreases in fees made by amendments pursuant to this paragraph shall not be subject to judicial review" *Id.* at 224); *see, Florida Health,* 830 F.3d at 522; *Sw. Airlines Co. v. TSA*, 554 F.3d 1065, 1071 (D.C. Cir. 2009). The courts have long recognized that even where judicial review is generally precluded by Congress, there is an exception to challenge an "'agency action in excess of jurisdiction.'" *Griffith v. Federal Labor Relations Authority*, 842 F.2d 487 (D.C. Cir. 1988). *Florida Health* even recognized that a regulation can be challenged when it is *ultra vires*, i.e. a "patent violation of agency authority". *Florida Health Sciences Center,* 830 F.3d at 522 (citations omitted).

The Court in *Florida Health* found that the regulations at issue there were not beyond the delegation of authority and therefore were not reviewable. They were not *ultra vires*. The regulations at issue here, on the other hand, can be reviewed because the Secretary drastically rewrote the statutory definition of an "applicable laboratory" by adding a requirement not in statute – that the laboratory be one that "bills Medicare Part B under its own National Provider Identifier (NPI)" (42 C.F.R. § 414.502). This was an act that the Secretary was not authorized to take. It was not part of the "agency's decision tree" (*Florida Health*, 830 F.3d at

521), because Congress had already defined that term and left no room nor delegated any authority to the Secretary to alter or amend the statutory definition. The Secretary's doing so nevertheless was beyond the statute's clear, unambiguous terms and delegation of authority to the Secretary, and showed a "patent violation of agency authority." *Florida Health*, 830 F.3d at 522.

The Court in *Florida Health* found that the action was not *ultra vires* because the "choice of data is not obviously beyond the terms of the statute." 830 F.3d at 262. There, unlike in the instant case, the Secretary was expressly charged with arriving at an "estimate" of the percentage of the nation's overall uncompensated care that each hospital provides. To do so, the Secretary had to decide upon what data to use to determine that estimate. *Id*.

The statute at issue in *Florida Health* barred judicial review of "any estimate of the Secretary for purposes of determining the factors described in paragraph (2)". 42 U.S.C. § 1395ww(r)(3). The "factors" gave broad discretion to the Secretary, including allowing estimates to be based on the "most recent estimates available" and for the uninsured, the "most recent period for which data is available". 42 U.S.C. § 1395ww(r)(2)(B). The

Secretary established the deadline for the "most recent estimates available" to be in March. Tampa General Hospital sought to give additional data outside the established deadline. The statute, however, not only barred review of any estimate, but also any period selected for such purposes. As such, the Court in *Florida Health* found that using a March 2013 cut-off for data did not patently violate the terms of the statute. 830 F.3d at 522.

The selection by the Secretary in *Florida Health* of the data collection period was a discretionary decision necessarily delegated to the Secretary by Congress and, thereby, inextricably intertwined with the estimate calculated. It is submitted, however, that if Congress had specified the data collection period and the Secretary had decided to ignore that period and restricted it by half, the result in *Florida Health* would have been different. That is analogous to what happened here.

The Decision in *Florida Health* should have caused the District Court to reach the opposite result in the instant case. Unlike in *Florida Health*, where the determination of what data to accept was expressly delegated to the Secretary, no such delegation was accorded the Secretary here to reject a critical definition already and definitively written by Congress.

The District Court's holding effectively allows the Secretary to enact any regulation he sees fit, even one that expressly conflicts with a statutory provision, because any definition employed by the Secretary will impact the data collected and the rates of payment calculated. For example, the District Court's holding would bar a challenge to agency action even if the Secretary simply lied about what the data said and what rates were calculated from them. Under the District Court's holding, the action would be inextricably intertwined with the rates and would therefore be unreviewable. Such extension of the "inextricably intertwined" doctrine, however, could obviously not go so far. Or, if the Secretary simply determined that the only "applicable laboratory" would be Quest, LabCorp, or some smaller laboratory, and did not collect data from any other laboratory, this determination too would be inextricably intertwined with the rates established, and under the District Court's holding, would be barred from judicial review. Lying about data or having one laboratory represent the entire market when the stated purpose of PAMA was to obtain data from the full private sector, would fly in the face of the congressional intent and the express statutory definition of "applicable laboratory," but would be unreviewable under the District

Court's holding. Such a result, however, could not logically be reached, and the reason in each case would be that such act would be *ultra vires*. So too, here, the actions by the Secretary in drastically limiting the scope of an already-defined term, "applicable laboratory," is a patent violation of the Secretary's authority under PAMA.

More on point than *Florida Health* is this Court's earlier decision in *Southwest Airlines v. TSA,* 554 F.3d 1065 (D.C. Cir. 2016). The statute and regulations at issue in *Southwest Airlines* involved the Aviation and Transportation Security Act ("ATSA"), which authorized the Transportation Security Administration (TSA) to charge airlines certain fees, but capped those fees at the amount that airlines paid "for screening passengers and property" in the time period prior to the agency being formed. 554 F.3d at 1068 (quoting 49 U.S.C. § 44940(a)(2)(B)(I) (repealed)). Under ATSA, Congress barred judicial review of "[d]eterminations of the Under Secretary" regarding the limitations on air carrier fees. *Id.* at 1069. When TSA calculated the fees, however, it included the screening costs for *non*-passengers as well as for passengers. While the Court concluded that it could not review the fee determinations made "for screening passengers and property," it invalidated the fee

determinations that included costs for screening *non*-passengers, because, as this Court held, the TSA violated the plain meaning of the statute when it included the costs for screening non-passengers. *See id.* at 1070. This Court was not persuaded by TSA's arguments that the phrase "screening passengers" was ambiguous, thereby allowing TSA to re-define the term to include "anything done to protect passengers." *Id.* at 1070. The Court found that "'ambiguity' is a creature not of definitional possibilities but of statutory context.'" *Id.*

Here, in enacting PAMA, Congress directed that

> Beginning January 1, 2016, and every 3 years thereafter… an *applicable laboratory (as defined in paragraph (2))* shall report to the Secretary, at a time specified by the Secretary, applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

42 U.S.C. § 1395m-1(a)(1) (*emphasis added*).

Congress went on to define an applicable laboratory as "a laboratory that, with respect to its revenues under [Medicare], a majority of such revenues are from [the Clinical Laboratory Fee Schedule or Physician Fee Schedule]." 42 U.S.C. § 1395m-1(a)(2). This case was brought because without authority to do so, the Secretary rejected the statutory definition

and substituted his own, adding that an "applicable laboratory" is one that "bills Medicare Part B under its own National Provider Identifier (NPI)".[2] 42 C.F.R. § 414.502. This rejection of the statutory definition is analogous to the attempted inclusion by the TSA of the costs of screening non-passengers. As the ACLA brief points out (ACLA Brief, Doc. 1763020, pgs. 63-66), the Secretary's adoption of an equation that includes Medicare fees paid for non-laboratory work of hospitals exceeds the bounds set by Congress for the Secretary to collect private payor data from all laboratories, a majority of whose revenues are derived from the clinical laboratory or physician fee schedules. Further, as ACLA points out, that means fees received by the laboratory for laboratory work, not fees received by other departments of the hospital for in-patient acute care, physical therapy, pharmacy or other services. (ACLA Brief, Doc. 1763020, pg. 64). The Secretary's delegation of authority to regulate the "parameters of data collection" is no more an invitation to redefine who has to report data than the TSA's authority to include the costs of screening non-passengers. *Sw.*

[2] An NPI number is a unique 10-digit identification number issued to health care providers, including laboratories, by the Centers for Medicare and Medicaid Services ("CMS").

Airlines, 554 F.3d at 1070-71.

As in the case of *Southwest Airlines*, the Secretary exceeded his authority in redefining what an "applicable laboratory" is when there was nothing ambiguous about that term in statute, and Congress did not grant any authority to the Secretary to modify that term by rulemaking.

There are two words in the term at issue, "applicable" and "laboratory". There can be no debate over what a "laboratory" is. The term has been statutorily defined since at least 1967 as follows:

> a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.
>
> 42 U.S.C. § 263(a).

This definition has never changed. It was continued when Congress enacted the Clinical Laboratory Improvements Amendments of 1988 ("CLIA '88"). Public Law 100-578 (1988). The well-understood meaning was affirmed in the Final Rule implementing performance requirements and other laboratory standards under CLIA'88. 57 Fed. Reg. 7,002 (Feb. 28, 1992). In implementing these regulations, codified at 42 C.F.R§ 493.2,

the Secretary also acknowledged that a laboratory is one that has a CLIA certificate or a state equivalent. 42 C.F.R. § 493.2. The definition is even adopted by many states. *See, e.g.* N.Y. Pub. Health Law § 571(1); Ga. Code. Ann. § 31-22-1(2); *see also*, Haw. Code. R. § 11-110.1. Inasmuch as the CLIA definition of a clinical laboratory is the only one existing in federal law, and that definition has also been adopted by the Department of Health and Human Services ("HHS"), Congress clearly understood and intended the term to have its long-standing and well-known meaning. The Secretary has not argued otherwise.

Nor can there be any credible dispute over which laboratories Congress determined would be "applicable" for purposes of data collection. Congress stated explicitly that an "applicable" laboratory is one a majority of whose Medicare revenues are from the Clinical Laboratory Fee Schedule ("CLFS") or the Physician Fee Schedule ("PFS"). 42 U.S.C. § 1395m-1(a)(2). Thus, Congress defined an "applicable" laboratory to be one whose Medicare revenues from the Clinical Laboratory Fee Schedule or Physician Fee Schedule exceeded 50% of its total Medicare revenues. There are no subparagraphs, exceptions or limitations to that definition. The only caveat in defining an "applicable laboratory" that Congress allowed for is to

permit the Secretary to "establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate." *Id.* This caveat to allow for low thresholds does not relate, however, to an NPI number, nor has the Secretary sought to justify the unique NPI additional criterion on that basis.

The PAMA statute here is clear and unambiguous as to what an applicable laboratory is. The Secretary exceeded his authority and acted *ultra vires* by rejecting that definition and applying a qualification of an NPI and therefore that act is subject to judicial review. "The question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has within the bounds of its authority*." *City of Arlington, Tex. v. F.C.C.*, 599 U.S. 290, 297 (2013). When an agency exceeds these bounds, "so that when they act improperly, no less than when they act beyond their jurisdiction, what they do is *ultra vires*." *Id.* The dispositive question is not whether the act of drastically altering the definition set by statute of an "applicable laboratory" was so inextricably intertwined with the establishment of payment amounts as to preclude judicial review, but whether doing so in the Final Rule exceeded

the authority of the Secretary. The answer, is yes.

CONCLUSION

The action by the Secretary in the Final Rule is not shielded from judicial review but is reviewable because the Secretary acted *ultra vires*. The Court should reverse the District Court's order dismissing ACLA's claims for lack of subject-matter jurisdiction.

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Respectfully submitted,

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Certificate of Compliance

This brief complies with the length limitations set forth in Federal Rules of Appellate Procedure 29(a), 32(a)(7) because it contains 3,017 words, as counted by Microsoft Word, excluding the items that may be excluded.

This brief complies with the typeface requirements of Fed. R. App. P. § 32(a)(5) and the type style requirements of Fed. R. App. P. § 32(a)(6) because this brief was prepared in 14-point Century Schoolbook font, a proportionately spaced typeface, using Microsoft Word 2013.

/s/ *R. Scott Caulkins*