IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR, II, In His Official Capacity as Secretary of Health and Human Services, U.S. Department of Health and Human Services Defendant.	)	Civil Action No.: 1:17-cv-02645-EGS

BRIEF OF AMICUS CURIAE

AMERICAN ASSOCIATION OF BIOANALYSTS

IN SUPPORT OF

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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IDENTITY AND INTEREST OF THE *AMICUS CURIAE*

The American Association of Bioanalysts ("AAB") submits this Brief in support of the motion for summary judgment by Plaintiff, 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 60 years. As more fully set forth in the Declaration of Mark S. Birenbaum, Ph.D., annexed hereto as Exhibit A ("Birenbaum Decl."), 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 will 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 engage in a full market study of private payor rates made to laboratories in all sectors of the 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".[1] The authority to file is by consent of all parties.

[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 the brief.

ARGUMENT

The Secretary's Final Rule improperly defines "applicable laboratory" (42 C.F.R. § 414.502) and creates a definition that is inconsistent with the PAMA statute (42 U.S.C. § 1395m-1(a)(2)). The definition under the Final Rule contravenes Congress's direction to the Secretary to obtain a market study of the private payor rates paid to laboratories that receive a majority of their Medicare revenues from the Clinical Laboratory Fee Schedule. The Final Rule promulgated by the Secretary contravenes the plain meaning of the statute, and the Secretary was not delegated authority by Congress to engage in rulemaking to redefine the statutory definition. To the extent that there is any ambiguity in the definition of an "applicable laboratory", the definition adopted by the Secretary is unreasonable, arbitrary and capricious.

POINT I

The Secretary Exceeded His Authority in Promulgating Regulations that Altered the Statutory Definition of "Applicable Laboratory"

The first question in any case challenging an agency's implementation of a congressional directive is whether the "intent of Congress is clear". *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778 (1984). When determining the "clarity and specificity of congressional intent expressed in [a] word…we recall that 'ambiguity is a creature not of definitional possibilities but of statutory context.'" *California Independent System Operator Corporation v. FERC*, 372 F.3d 395, 400 (D.C. Cir. 2004) (*citations omitted*).

A. The definition of "applicable laboratory" in statute is clear

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, and this Amicus Brief is needed, 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 case should begin and end with the question of whether the intent of Congress is clear, because there is nothing ambiguous about how Congress defined an "applicable laboratory" and Congress did not grant any authority to the Secretary to redefine or 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

[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").

> 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.

Nor can there be any credible dispute over which laboratories Congress determined would be "applicable" for purposes of data collection, yet that is the very matter at issue here. 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 simply 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.* Significantly, Congress did not direct the Secretary to establish low thresholds by notice and comment rulemaking. *See* 42 U.S.C. § 1395m-1(a)(2), (12). This caveat to allow for low thresholds does not relate, however, to a NPI number, nor has the Secretary sought to justify the unique NPI additional criterion on that basis.

In *Utility Air Regulatory Group v. EPA*, the United States Supreme Court addressed the question whether the Environmental Protection Agency (EPA) permissibly interpreted the Clean Air Act to provide that a source may be required to obtain a permit on the sole basis of its potential for greenhouse-gas emissions. 134 S.Ct. 2427, 2434, 2438 (2014). Prophetically addressing the Secretary's rewriting of the express statutory definition of "applicable laboratory," the Court stated in *Utility Air*:

> We conclude that EPA's rewriting of the statutory thresholds was impermissible and therefore could not validate the Agency's interpretation of the triggering provisions. An agency has no power to "tailor" legislation to bureaucratic policy goals by rewriting unambiguous statutory terms. Agencies exercise discretion only in the interstices created by statutory silence or ambiguity; they must always "'give effect to the unambiguously expressed intent of Congress.'" *National Assn. of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 665,127 S. Ct. 2518, 168 L. Ed. 2d 467 (2007)* (quoting *Chevron, 467 U.S., at 843, 104 S.Ct. 2778, 81 L. Ed. 2d 694*). It is hard to imagine a statutory term less ambiguous than the precise numerical thresholds at which the Act requires PSD and Title V permitting. When EPA replaced those numbers with others of its own choosing, it went well beyond the "bounds of its statutory authority." *Arlington, 569 U.S., at ___, 133 S.Ct. 1863, 185 L. Ed. 2d 941, 951* (emphasis deleted). *Id*. at 2445.

As the EPA did in *Utility Air*, the Secretary has also exceeded his authority in rejecting the unambiguous statutory definition of "applicable laboratory" and substituting his own. The statute

clearly directs that an "applicable laboratory" shall report to the Secretary, "applicable information" for a "data collection period" for each clinical laboratory test. 42 U.S.C. § 1395m-1(a)(1).

As shown in the succeeding section of this Brief, the absence of ambiguity to the term is reflected in the limited delegation of rulemaking authority, which did not extend to rejection of the statutory definition and the substitution of an agency-preferred definition.

B. Congress did not delegate to the Secretary authority to determine from which laboratories to collect data

Since the term "applicable laboratory" is unambiguous, because Congress specified exactly what it meant by such term, there is no need to move to extrinsic evidence to help the Court in construction of the statutory language, or to reach step two of the *Chevron* analysis, i.e. whether the regulation is reasonable. The absence of a need for rulemaking to further define this term was recognized by Congress, which did not delegate any authority to the Secretary to promulgate regulations defining the term "applicable laboratory," or which laboratories to exempt from the data reporting requirements other than for low thresholds.

The need for an agency to stay within the rulemaking bounds created by Congress was heavily addressed in *Gonzales v. Oregon,* where the Supreme Court emphasized that a "rule must be promulgated pursuant to authority Congress has delegated to the official." 546 U.S. 243, 258 (2005). The "starting point for this inquiry is, of course, the language of the delegation provision itself." *Id*.

As the Supreme Court emphasized, agencies may only implement regulations when Congress delegates such authority, and it is only when there has been a delegation of such authority by Congress that the agency rulemaking is accorded deference. *Gonzales*, 546 U.S. at 258. In *Gonzales*, the Attorney General issued an Interpretive Rule addressing the implementation of the Controlled Substances Act ("CSA") with respect to the Oregon Death with Dignity Act and

prohibited physicians from prescribing controlled substances under State law. *Id*. In *Gonzales*, the express delegation of authority read:

> "(1)The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and to listed chemicals; and (2) The Attorney General may promulgate and enforce any rules, regulations and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter. *Id.* at 259.

Despite the broad delegation in *Gonzales*, the Supreme Court stated that the Attorney General was delegated authority to promulgate rules "relating only to 'registration' and 'control,' and 'for the efficient execution of his function' under the Statute.'" *Id*. The term "control", however, was a term of art, and the term "registration" was clearly defined, such that the Attorney General could not rely upon the subdivision (1) delegation to support his authority to issue his Interpretative Rule. *Id*. at 260. As to the second delegation "though it does require the Attorney General to decide '[c]ompliance' with the law, it does not suggest that he may decide what the law says." *Id*. at 263. *See also, Sutton v. United Air Lines, Inc.*, 527 U.S. 471 (1999).

The delegation of authority under PAMA is not nearly as broad as in *Gonzales*. With respect to PAMA, Congress specifically limited what was a proper subject of PAMA notice and comment rulemaking to the "parameters for data collection." *See* 42 U.S.C. § 1395m-1(a)(12). Thus, the PAMA statute specifically states:

> Regulations. Not later than June 30, 2015, the Secretary shall establish through notice and comment rulemaking parameters for data collection under this subsection. 42 U.S.C. § 1395m-1(a)(12).

Directing the Secretary to establish the parameters for data collection, however, is not an invitation to the Secretary to amend, modify, restrict, alter or limit in any way what laboratories

Congress defined as being "applicable." The only question Congress left to the Secretary regarding which laboratories were "applicable" was to set low volume or low expenditure thresholds.

That Congress did not extend its delegation of rulemaking authority to amend the definitions set by the statute is reflected in subsection (a)(1). There, Congress introduces the reporting obligation by stating that an applicable laboratory "as defined in paragraph (2)" shall report applicable information "as defined in paragraph (3)" for a data collection period "as defined in paragraph (4)." 42 U.S.C. § 1395m-1(a)(1) (underlined for emphasis). These provisions do not say "as defined by the Secretary;" they say as defined in the succeeding sections. Thus, they refer explicitly to, and set the reporting obligations for "applicable" laboratories as defined in paragraph (2).

In contrast to the above explicit references to the definitions below for "applicable laboratory," "applicable information," and "data collection period," the statute did not refer to a definition below in using the phrase "furnishes during such period for which payment is made" 42 U.S.C. § 1395m-1(a)(1). Thus, what Congress did leave for the Secretary to accomplish by rulemaking in the first subsection of (a)(1) was the singular issue for which the Secretary's expertise was needed, i.e., how to collect the applicable information for each clinical diagnostic laboratory test that each applicable laboratory furnished. Because Congress expressly limited the rulemaking to the parameters of data collection "under this subsection," the Secretary is without authority to rely upon any other statutory delegation of rulemaking authority. While Congress did also allow the Secretary to establish low thresholds, it did not require that they be done by regulation. Similar to *Gonzales*, therefore, the delegation of authority was limited, and the Secretary was not empowered to decide what the law is, but rather just to arrange for the required data to be collected. *See, Gonzales*, 546

U.S. at 262. The Secretary was instructed to promulgate regulations setting "parameters for data collection." 42 U.S.C. § 1395m-1(a)(12). The Secretary was no more delegated the authority to redefine an "applicable laboratory" as it was to redefine "applicable information" or the use of a weighted median. *See, e.g. Gonzales,* 546 U.S. at 259.

This Circuit has also recognized that when Congress specifically defines the permissible areas of rulemaking, the administrative agency does not enjoy the right to promulgate regulations in other areas for which Congress has spoken unambiguously. In *Backcountry Against Dumps v. EPA,* 100 F.3d 147 (D.C. Cir. 1996), Petitioners challenged the EPA for approving a waste program by an Indian tribe that was submitted in accordance with a draft implementation rule that permitted Indian tribes to submit waste permit programs for agency review. Under the Resource Conservation and Recovery Act, only States, not municipalities, were permitted to submit programs for review by the agency and Congress had specifically listed Indian Tribes in the definition of a "municipality," not as a State. *Backcountry Against Dumps,* 100 F.3d at 149-150. This Circuit found that the statute was clear on its face in defining the term "State," holding that the agency had exceeded its authority in implementing this rule. *Id.* at 150. The Court stated that "were courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely with the Constitution as well.'" *Id*. at 151; *see also, American Bankers Ass'n v. NCUA*, 38 F.Supp.2d 114 (D.D.C. 1999) (collecting cases and finding that the NCUA had exceeded its authority when implementing regulations that violated the specific statutory prohibition). As the courts found in *Backcountry Against Dumps* and *American Banker Ass'n,* agencies are not permitted to engage in rulemaking that contradicts the statute or where Congress has not delegated such rulemaking authority.

Congress was very clear when enacting PAMA – the Secretary was permitted to establish a low threshold or volume amount for which rulemaking was not even needed, and parameters for data collection for which rulemaking was needed. 42 U.S.C. § 1395m-1(a). Congress did not permit the Secretary to redefine what is an "applicable" laboratory. Yet the Secretary here engages in the same overreaching that the agencies in *Backcountry Against Dumps* and *American Bankers Ass'n* engaged in, justifying a rulemaking that exceeds the statutory delegation of authority by arguing (wrongly) that the statute is ambiguous.

C. The Secretary's reason for contradicting the statute's definition is unavailing

Despite many commentators objecting to the Secretary's proposed definition of an "applicable laboratory," noting that this would exclude hospital laboratories from reporting and therefore would not be a true market study as intended by Congress, the Secretary rejected Congress's definition of "applicable laboratory," because "we also believe hospitals would object to using the CLIA certificate as commentators advocate." 81 Fed. Reg. 41,036, 41,046 (June 23, 2016). Defendant's "belief," however, that hospitals "may object" is hardly a ground for disregarding unambiguous statutory language. Such unsupported speculation stands in sharp contrast to the real and vocal objections of the rest of the laboratory industry. Nor is it a task of such magnitude that one must say that Congress could not have intended exactly what it had said.

Hospital outreach laboratory services are simply revenue or cost centers of hospitals. Separately identifying the revenues the laboratory receives from Medicare Part B as opposed to Part A is simple and standard practice. It is customary practice to do so for every revenue or cost center. For example, New York regulations require annual reports from hospitals that reflect revenues and expenses for each cost and revenue center:

> For example, expenses related to the clinical laboratory functions (activities) are included in the Laboratory Services-Clinical cost center (account 7210) and related revenue are to be included in Laboratory Services-Clinical revenue center (account 4210). 10 N.Y.C.R.R. §442.12(e).

The Secretary should also be familiar with this concept as the Centers for Medicare & Medicaid Services requires that Medicare-certified institutional providers submit "utilization data, cost and charges by cost center". *See* "Cost Reports", Centers for Medicare & Medicaid Services, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/. There is no basis, therefore, to alter the statutory definition by claiming that hospitals would object or be inconvenienced by having to access this data. They do so regularly, and the Secretary knows this by virtue of his own required cost reports by cost center.

The Secretary's further contention, that he can require a "laboratory" to have a unique NPI number because the PAMA statute should be read to allow HHS to "limit[] reporting to primarily independent laboratories and physician office laboratories," 81 Fed. Reg. 41036, 41,046 (June 23, 2016), simply enjoys no support in the statutory language or legislative history. The statute says no such thing, nor does it implicitly support that interpretation. Congress not only directed that the Secretary collect applicable information from all laboratories that receive a majority of their revenue from the fee schedules (42 U.S.C. § 1395m-1(a)(2)), but it also expressly stated that the PAMA payment rates would apply as well to tests furnished by a hospital laboratory if the tests were paid for separately, and not as part of a bundled payment. 42 U.S.C. § 1395m-1(b)(1)(B).

The fact that Subdivision 1395m-1(b)(1)(B) makes clear that hospitals were covered for payment purposes if rates were not bundled shows that where Congress believed there was a question as to whether hospital laboratories should be specifically addressed, it did so. Congress did not

define an applicable laboratory to be one that receives a majority of its Medicare revenue from the fee schedule, except for hospital laboratories. If Congress had intended to exclude hospital, or to rely upon a unique NPI number, it would have said so.

D. Legislative design

The definition at issue here is also inconsistent with legislative design. As explained in *Gonzales*, the court may look to legislative design to see whether the rule would create "considerable tension with the narrowly defined delegation" made by Congress. *Gonzales*, 546 U.S. at 264. As such, in a step one *Chevron* analysis, courts may look to the statute's legislative history. *Shays v. FEC*, 337 F.Supp.2d 28 (D.D.C. 2004); *see also*, *Gonzales*, 546 U.S. at 269.

Congress enacted PAMA to address the sustainable growth rate and determined that the payment system to the laboratories was outdated. 160 Congressional Record H2700, 2714 (daily ed. March 27, 2014). Congress wanted a full market study of payments made to *all* laboratories by private payors. Senator Burr stated, and Senator Hatch confirmed, that the "intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that *all sectors* of the laboratory market should be represented in the reporting". 160 Cong. Rec. S2800 (daily ed. May 8, 2014). Congress, therefore, intended that all laboratories, whether national laboratories, regional, community, physician office or hospital laboratories that receive a majority of their revenue from the Clinical Laboratory Fee Schedule or Physician Fee Schedule be included in the market study, except to the extent the Secretary set a low volume or low expenditure threshold. *See* 160 Cong. Rec. S2860. If Congress had wanted to include only independent laboratories, it would have stated so explicitly and not clarified the term by including a "majority of revenues" requirement. *See generally*, 42 U.S.C. § 1395m-1(a).

Similar to *California Independent System Operator Corporation*, 372 F.3d at 401, 404, Congress has specifically limited the rulemaking authority of the Secretary. In subsection (a)(12), Congress delegated rulemaking authority over one singular issue, the parameters for data collection, i.e. how to collect the "applicable information." The term "laboratory" has a well-accepted meaning, and Congress supplied the meaning to the term "applicable." Congress did not give authority to the Secretary to alter that. Congress would not have defined "applicable" by reference to a "majority" standard for Medicare revenues, or created just one allowable exception, i.e. a volume threshold, if Congress had intended to allow the Secretary to define this term himself. The Secretary has constructed a definition that is a "sufficiently poor fit with the apparent meaning of the statute." *Cal. Indep. Sys. Operator Corp.*, 372 F.3d at 401.

POINT II

The Secretary's Definition Is Unreasonable and Defeats the Stated Purpose of PAMA

While there is no ambiguity to the term "applicable laboratory" as discussed in Point I, even if there were, and even if Congress had authorized rulemaking over the statutory delegation such that the Court must proceed to step two of the *Chevron* analysis, the Secretary's definition of "applicable laboratory" still cannot stand. A regulation may stand where the "statute is silent or ambiguous with respect to the specific issue," Congress delegated rulemaking authority with respect to the matter at issue, and then only if the agency gave a reasonable interpretation. *Chevron*, 467 U.S. at 843-844. The test of reasonableness, "overlaps with the arbitrary and capricious standard," *Shays v. FEC*, 414 F.3d 76, 96 (D.C. Cir. 2005), and the Secretary cannot simply create a rule where the interpretation negates the stated purpose of the statute. *King v. Burwell*, 135 S.Ct. 2480 (2015). The Secretary's

limitation on the Final Rule as to which laboratories are "applicable" for purposes of data reporting, beyond that expressly stated by Congress, is unreasonable. It defeats the purpose of PAMA, will force laboratories to close or cutback on services, and will deprive Medicare beneficiaries and other patients of access to care.

Where a term appears to be ambiguous, other statutes and the overall statutory scheme can provide clarification. *Burwell,* 135 S.Ct. 2492. "Reasonable statutory interpretation must account for both "the specific context in which . . . language is used" and "the broader context of the statute as a whole." *Util. Air Regulatory Group*, 134 S. Ct. at 2442. If the agency's interpretation is inconsistent with the overall framework, the interpretation must fail. *Id*. In *Utility Air Regulatory Group v. EPA,* discussed *supra* Part I(A), the Court noted that what may seem to be an ambiguous statutory provision in isolation is

> [o]ften clarified by the remainder of the statutory scheme…because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *United Sav. Assn. of Tex. v. Timbers of Inwood Forest Associates, Ltd., 484 U.S. 365, 371 (1988)*. Thus, an agency interpretation that is "inconsisten[t] with the design and structure of the statute as a whole," *University of Tex. Southwestern Medical Center v. Nassar, 570 U.S. ___, ___, 133 S. Ct. 2517, 186 L. Ed. 2d 503 (2013),* does not merit deference. *Id*. at 2427.

In the instant case, no deference should be given to the Secretary because his rejection of the statutory definition and substitution with his own definition is inconsistent with the "design and structure" of the PAMA statute. The Medicare Act of 1965 was designed to

> provide a hospital insurance program for the aged under the Social Security Act with a supplementary medical benefits program and an expanded program of medical assistance, to increase benefits under the Old-Age, Survivors, and Disability insurance System, to improve the Federal-State public assistance programs, and for other purposes. 89 P.L. 97, 79 Stat. 286, 89 P.L. 97, 79 Stat. 286 (July 30, 1965).

PAMA was enacted to control the sustainable growth rate and to continue to promote access to services for Medicare beneficiaries. 160 Cong. Rec. H2700. Congressman Upton, Chairman of the Energy and Commerce Committee, when debating the passage of PAMA, stated that the purpose of this statute was to "ensure that seniors' access to quality health care is not jeopardized as we continue the effort to permanently resolv[e] this broken system". 160 Congressional Record H2700, 2714 (daily ed. March 27, 2014). The Secretary's unauthorized rejection of the statutory definition of "applicable laboratory" will defeat this purpose because it will jeopardize the aged and disabled by reducing or eliminating their access to laboratory services. Those most at risk are those with fewer choices of providers, and where providers are most susceptible to dramatic swings in rates of payment.

As Plaintiff's and Amicus AAB's Declarations reflect, those at most risk may be beneficiaries residing in nursing homes or rural areas, or the homebound. One laboratory servicing a nursing home has already closed and others are in the process of reducing or eliminating services. *See*, *Declaration of Annette Iacono,* ¶ 19, annexed as Exhibit B ("Iacono Decl."); *Declaration of Thomas Kennedy*, ¶ 16, annexed as Exhibit C ("Kennedy Decl."); *Birenbaum Decl.*, ¶ 16. These disastrous consequences could not have been what Congress intended, as they defeat the purpose of the Medicare Act and PAMA to protect and sustain beneficiary access to care. Iacono Decl., ¶ 19-21; Birenbaum Decl., ¶ 22, 24; Kennedy Decl., ¶ 17. As was the case in *Utility Air Regulatory Group*, the Secretary's rejection of the statutory definition is not reasonable and is incompatible with the statutory scheme because of the enormous burdens it would cause. *See Id*. at 2443.

Rather than cause these enormous burdens on the system, Congress wanted a full market study of the private payor rates in order to inform and determine Medicare payment rates by

expressly instructing how the rates would be revised in order to ensure sustainability of the system. *See* 42 U.S.C. § 1395m-1(b)(1). What Congress did not intend to do was reduce or eliminate services to beneficiaries. As was acknowledged by the Secretary, the "purpose of the revised Medicare payment system is to base CLFS payment amounts on private payor rates". *See* 81 Fed. Reg. at 41,046. By virtue of these regulations, however, the Secretary decided to collect data principally from independent laboratories, and most of that data coming from Quest Diagnostics and LabCorp. But the rates paid to these laboratories are not representative of rates paid to the full market, for two principle reasons. First, the rates do not reflect the much higher rates paid for hospital outreach services. Second, by virtue of their very great volume, these two laboratories have captured exclusive or preferred provider contracts all over the country by offering highly discounted rates. These discounted rates are not reflective of the higher dollar rates paid to most other independent clinical laboratories.

The Supreme Court in *King v. Burwell* held that the consequences of an agency interpretation can be a decisive factor in assessing congressional intent. The issue in *King v. Burwell* was whether tax credits under the Affordable Care Act ("ACA") were available in States that had a Federal Exchange as opposed to a State Exchange. 135 S.Ct. at 2487. The petitioner in *Burwell* argued that ACA tax credits were only available in states with a Federal Exchange, but the Court disagreed, finding that this interpretation "would destabilize the individual insurance market in any State with a Federal Exchange, and likely create the very 'death spirals' that Congress designed the Act to avoid." *Id.* at 2493 (*citation* omitted). The Court found that it was "implausible that Congress meant the Act to operate in this manner," finding that each provision was meant to apply in every state. *Id*. at 2493-94.

The unreasonableness of the revised definition is evident by the data that was ultimately reported. The market study excluded virtually all hospital and physician office laboratories. *See* Birenbaum Decl. ¶ 23. CMS reported that the data is comprised 90% of independent laboratories.[3] This is consistent with HHS' comments that they believed they were entitled to limit the data collected to those independent laboratories, despite Congress' clear directive otherwise. *See*, 81 Fed. Reg. at 41,045 – 6. The data ultimately collected, however, is not representative of the national laboratory market. Fewer than 2,000 of the more than 260,000 laboratories nationwide, just 0.7 percent, reported private payor information to the Secretary. *See* Declaration of Julie Khani, ECF DKT 1-4, ¶ 19 ("Khani Decl."). Only 21 of approximately 7,000 hospital laboratories reported data. Khani Decl., ¶ 10. Despite representing 26% of the Medicare payments for laboratories in 2016, hospital laboratories accounted for just 1% of the reported data. Khani Decl, Exh. 35, p. 4. Further, 90% of the data was reported by independent laboratories and 60% of the universe of data was reported by just the three largest laboratories, while they together represented just 16% of the 2016 Medicare market. *Id.* Purposefully excluding most hospital laboratories from the reporting requirements, therefore, ensures that the stated purpose of Congress is not met – to collect market data of private payor rates from all sectors of the laboratory industry to ensure that reimbursement under the Clinical Laboratory Fee Schedule or Physician Fee Schedule is comparable to what is paid in the private market.

[3] Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalFeeSchedule/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf

The Secretary's decision to exclude hospital laboratories is further in conflict with the context of the statute because the statute requires that the rates established by the market study will apply to all clinical diagnostic laboratory tests furnished, even by "a hospital laboratory if such test is paid for separately". 42 U.S.C. § 1395m-1(b)(1).

Similar to *Burwell* and *Utility Air*, the Secretary's inclusion of a unique NPI number to the definition of an "applicable laboratory" will create a "death spiral" and negate the purpose of PAMA to develop a full market study to calculate rates that will sustain the growth of the Medicare program and ensure access to care for beneficiaries. Laboratories are already reducing services. *See, Iacono Decl.*, ¶¶ 16, 19; *Kennedy Decl.*, ¶ 16. It is just a matter of time before laboratories will have to close, leaving unattended breaches in the network of services for Medicare beneficiaries.

Any argument by the Defendant that these are consequences that marginal laboratories would experience anyway even if the PAMA rates were calculated using a broader definition of "applicable laboratory" is unavailing and misses the point. Congress concluded that the rates that would result from a full market study would further, not defeat, the objectives of the Medicare program. That is where Congress decided to draw the line, and that line has to be respected by the Secretary. There is an enormous difference between rates that effect a $100 million reduction in payments nationwide for laboratory services as was originally estimated by the Congressional Budget Office in 2014, versus a $670 million reduction that is currently estimated based on the new payment rates. The Secretary may wish to reduce expenditures to that much greater level, but Congress did not grant such authority to do so. It envisioned more moderate reductions based upon what a full market analysis of the weighted median would produce.

Far from carrying out the statute's purpose of ensuring that Medicare patients have

sustainable access to clinical laboratory services, the Secretary's Final Rule serves to reduce such access. This is not what Congress intended.

CONCLUSION

For the above reasons, Amicus AAB requests that this Court grant Plaintiff's summary judgment motion and enjoin the Secretary to (1) establish parameters for data collection that include data from hospital outreach laboratory services, (2) calculate new rates based upon such data, and (3) reinstate 2017 rates pending determination and publication of such new rates.

DATED: February 21, 2018

Respectfully submitted,

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American Association of Bioanalysts

EXHIBIT A

TO

BRIEF OF AMICUS CURIAE AMERICAN ASSOCIATION OF BIOANALYSTS

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR, II, In His Official Capacity as Secretary of Health and Human Services, U.S. Department of Health and Human Services Defendant.	Civil Action No.: 1:17-cv-02645-EGS

DECLARATION OF MARK S. BIRENBAUM, Ph.D.

I, MARK S. BIRENBAUM, Ph.D., declare the following to be true and correct to the best of my knowledge:

1. I am the Administrator of American Association of Bioanalysts ("AAB"), and I submit this Declaration as part of the Amicus submission of AAB in support of the Plaintiff American Clinical Laboratory Association's Complaint and motion for summary judgment. This Declaration is also submitted in support of the motion for leave to file an amicus brief on behalf of AAB. I am fully familiar with the facts and circumstances stated below.

2. AAB is a not-for-profit corporation chartered in 1957 under the laws of the State of California, and maintains its principal place of business at 906 Olive Street, Suite 1200, St. Louis, Missouri. The primary purpose for which AAB was formed was "to foster and expand the scientific, economic and public health interests of bioanalytical

laboratories; to safeguard their economic interests; and to establish proper professional ethics for those engaged in the profession."

3. AAB has continually represented the clinical laboratory community for 60 years, during which time AAB has continued to advocate on behalf of independent clinical laboratories in many forums, including Congress, Federal regulatory agencies such as the Department of Health and Human Services ("HHS") and the Food and Drug Administration, as well as state legislatures and state regulatory agencies. In addition to protecting the interests of its members, AAB has been a leader in the fight for accessibility to the highest quality clinical laboratory services, including for Medicare beneficiaries. On behalf of its members and the general public, AAB has advocated on virtually all federal issues affecting clinical laboratories and the populations they serve, including issues of Medicare reimbursement, conditions of participation, personnel standards, the Clinical Laboratory Improvement Act of 1967 ("CLIA '67") and the Clinical Laboratory Improvement Amendments of 1988 ("CLIA '88"), as well as many issues before state legislatures and administrative agencies.

4. In 1968, AAB founded an independent certifying board for clinical laboratory directors, called the American Board of Bioanalysis ("ABB"). ABB became one of only four certifying boards for clinical laboratory directors recognized in the original Medicare / CLIA '67 regulations, and ABB continues to be recognized under the CLIA '88 regulations and most state laboratory personnel regulations. Today, ABB also certifies technical supervisors and clinical consultants, in addition to five levels of clinical laboratory directors. ABB is also the major certifying board for laboratorians in assisted reproductive technology laboratories.

5. A major concern of AAB throughout its history has been to improve the quality of clinical laboratory services. To that end, AAB established a Proficiency Testing Service ("PTS"). Proficiency testing is one of the central safeguards of laboratory quality under CLIA '67 and CLIA '88 and their implementing regulations. Proficiency testing involves the testing of unknown samples sent to a laboratory by an HHS-approved PT program. Most sets of PT samples are sent to participating laboratories on a scheduled basis. PT, therefore, serves as an external quality control tool used by laboratories as well as by CMS and accrediting organizations to monitor laboratory performance.

6. AAB's PTS is accepted by HHS for CLIA and Medicare purposes. It is also accepted by the College of American Pathologists and almost every state licensing body. As one of the largest PT programs in the country, AAB's PTS enrolls over 4,000 laboratories.

7. Throughout its history, AAB has also attempted to facilitate cooperation and communication between laboratory and professional associations. For example, AAB was involved in the formation of the Intersociety Committee of Laboratory Services Related to Health, which eventually became the National Council on Health Laboratory Services ("NCHLS"). After the NCHLS was disbanded in the 1980s, AAB was instrumental in the formation of the Clinical Laboratory Coalition, which became an effective laboratory coalition for dealing with Medicare and other important legislative and regulatory issues.

8. Over the years, AAB has also represented or supported the clinical laboratory community in several litigations, including a 2008 lawsuit commenced in

Federal Court in California that led to an injunction halting a competitive bidding demonstration project for Medicare. Further, beginning in the 1980s, and continuing through 2013, AAB led a series of actions against the New York State Department of Health in state court in New York in three separate actions, challenging the excessive fees imposed upon clinical laboratories by the Department of Health. Those lawsuits led not only to a change in the method of calculating appropriate charges, but New York licensed laboratories also collected over $23 million in refunds from the State.

9. In 2006, AAB established a special interest group called the National Independent Laboratory Association ("NILA") that has become the voice of community and regional clinical laboratories and has participated in a number of important legislative and regulatory battles, including competitive bidding, copayments for laboratory services, the Affordable Care Act and the Protecting Access to Medicare Act of 2014 ("PAMA").

10. Today, AAB/NILA is the principal clinical laboratory trade association representing the interests of community and regional clinical laboratories nationwide. AAB/NILA's members generally are those that would be most affected by the Secretary's final rule rewriting the definition of "applicable laboratory," which is being challenged in this action.

11. Attached as Exhibit "A" is a map of the United States showing where AAB/NILA member laboratories are physically located. As the Court can see, AAB/NILA laboratories are spread out all over the continental United States. Over 75% of AAB/NILA members qualify as "small businesses" under the Small Business Administration definition (*see* 13 C.F.R. Part 121 and associated table).

12. By service type, AAB/NILA laboratories are also representative of the clinical laboratory industry nationwide. For example, 36% of AAB/NILA laboratory members are full service labs, and the rest have various specialties. Many AAB/NILA laboratories specialize in fields such as microbiology, immunology/allergy, molecular diagnostics, anatomic pathology, toxicology, and others.

13. It is important to point out that only a few of AAB/NILA laboratories primarily service skilled nursing facilities, like Brookside Medical Laboratories does (see Iacono Declaration). This dearth of nursing home laboratories is representative of the industry as a whole. As explained by Ms. Iacono in her Declaration, there is little economic incentive for laboratories to be dedicated primarily to the nursing home population, and the more difficult it becomes to carry on that business, the fewer such laboratories will exist.

14. AAB/NILA laboratories are generally community-based, are geographically dispersed and often serve rural communities. Many do not have large service menus or client populations, so they do not have the ability to subsidize losses from one payment stream with profits derived from others.

15. The Secretary recognized this problem in stating that "Rural laboratories are not likely to have the test volume and corresponding revenue to meet the low expenditure threshold, that is, at least $12,500 in CLFS revenue during the data collection period." *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalFeeSchedule/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf* ("CMS Summary of Reporting") at pp. 3-4. The significance is a recognition by the Secretary of the comparatively low volume of testing performed by laboratories

servicing rural areas. While they are exempted from reporting requirements, they are not exempted from the wrongly-achieved Medicare cuts to their rates that the Secretary's definition of "applicable laboratory" causes. This must invariably lead to reduced access to laboratory services in rural communities.

16. As Administrator of AAB/NILA, I am in continuous contact with our members and am acutely aware of their financial problems and the impact that HHS' unlawful exclusion of hospital outreach laboratory data will have on their future. For example, on January 26 and 27, 2018, we held a conference in San Diego for NILA members, a principal subject of which was the anticipated impact that the Secretary's final rule will have on their laboratories. One of our member laboratories, a laboratory that serviced skilled nursing facilities in New Jersey, has already closed as a result of the Secretary's failure to faithfully implement PAMA. Another multi-state health system laboratory serving patients in Oregon and Washington, which was a NILA member in 2017, reported that year that it decided to sell its outreach laboratory business to one of the two largest national laboratories, largely as a result of anticipated cuts to the Part B clinical laboratory fee schedule resulting from the Secretary's failure to collect the market data that Congress required, which in turn has resulted in drastic cuts in Medicare payment rates. It was further reported that as a result of the sale, 400-500 jobs were lost. Virtually every other NILA member expressed that the Secretary's failure to comply with PAMA will inevitably result in some or all of the following: closing of their laboratories, reducing services, eliminating tests, laying off employees, and restricting the geographical area that is being serviced, all of which will decrease services to Medicare beneficiaries.

17. On behalf of AAB and NILA, I and/or our Washington representatives have been in frequent contact and communication, including meetings, with representatives of HHS and the Centers for Medicare and Medicaid Services ("CMS"), for the purpose of addressing problems created by the then-proposed PAMA regulations. Among the issues that were prominent was the definition of "applicable laboratory" that was being offered by HHS in the proposed regulations. These meetings took place in 2015, 2016 and 2017, were attended by senior administration officials, including the CMS Director of Medicare, and other senior advisors to former HHS Secretary Price.

18. It became obvious to AAB that the proposed definition of "applicable laboratory" was inconsistent with Congressional intent and was purposefully designed to defeat the language of the PAMA statute and the purpose for which Congress directed that full market data on commercial payor rates for clinical laboratory services be reported and collected.

19. Through discussions with Congressional representatives, and the language of the PAMA statute itself, we understand that Congress wanted Medicare reimbursement for clinical laboratory services to be more aligned with what was being paid by commercial payors for the same services, but with the understanding that Congress wanted to promote access to services for Medicare patients. To that end, Congress directed the Secretary to receive and analyze data from ***all*** laboratories that receive a majority of their Medicare revenues from the clinical laboratory fee schedule or the physician fee schedule. There was no exclusion stated in the PAMA statute that intended or directed the Secretary to promulgate regulations that would exclude many of the highest reimbursed laboratories from that market data, *i.e.*, hospital outreach laboratories.

20. In fact, Congress did not even authorize the Secretary to define the term "applicable laboratory" by rulemaking; Congress directed the Secretary only to issue regulations over how data was to be collected. *See* 42 U.S.C. 1395m-1.

21. The addition to the definition of "applicable laboratory" by the Secretary of the NPI number had to have been purposefully done to reduce laboratory reimbursement well below that which Congress would have intended by acquiring such data from ***all*** clinical laboratories. It is no secret, and it had to have been known to the Secretary, as it would have been known to Congress, that hospital outreach laboratories are generally reimbursed in amounts far in excess of that paid to independent clinical laboratories. The Secretary also knew how few hospital outreach laboratories had their own NPI number and that this factor alone would exclude hospital laboratories from the data reporting obligations. It is my best understanding that hospital laboratories are reimbursed by private payors on average as much as 2-3 times what independent clinical laboratories are reimbursed.

22. Significantly, CMS claims that the changes in laboratory prices that are now in effect will save Medicare Part B approximately $670 million in calendar year 2018 alone. The primary reason for that, however, is the Secretary's failure to comply with Congress's directives, which, as discussed above, will put laboratories out of business, reduce the quality of laboratory services, impair accessibility, and hurt patient care, particularly those patients whom Medicare was intended to benefit.

23. The methodology adopted by the Secretary for PAMA reporting does not achieve the market-based analysis that Congress required in the PAMA statute. For example, by reason of the definition of "applicable laboratory," virtually all hospital and

most physician office laboratories were excluded, which laboratories comprise approximately half of the Medicare clinical laboratory fee schedule volume. Only 21 of 2,311 hospitals nationwide reported data. *See* CMS Summary of Reporting, p. 3.

24. It was Congress' directive for the Secretary to ascertain what all laboratories that received a majority of their Medicare revenues from the clinical laboratory fee schedule or the physician fee schedule were being paid for each clinical laboratory test. The purpose was for the Secretary to determine a true picture of the amounts being paid by private payors, so that Medicare rates could be adjusted to be more in harmony with that market basket of payments. While it was expected that this data would result in some reduction of laboratory payments by Medicare, Congress did not direct that the statute be implemented in such a way as to purposefully drive rates down to such an extreme level that laboratories would not be able to survive. Congress, rather, wanted to ensure Medicare patients had sustainable access to clinical laboratory services. Congress did not direct that hospital laboratories be excluded, nor did Congress direct that the Secretary should add having a unique NPI number to the definition of what is an applicable laboratory. Congress did not even delegate to the Secretary the right to redefine what laboratories were "applicable" other than to establish low threshold criteria.

25. The term "laboratory" is unambiguous, as it has long existed in CLIA '67, CLIA '88 and the implementing regulations.[1] And since the purpose of PAMA is to set Medicare rates for participating CLIA laboratories, the CLIA definition had to have been

[1] "Laboratory" or "clinical laboratory" is defined in 42 U.S.C. § 263a(a) to mean "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."

what was intended by Congress. The word "applicable" is also clearly defined as a laboratory " a majority of [whose] such revenues are from [the Clinical Laboratory Fee Schedule and Physician Fee Schedule]." 42 U.S.C. § 1395m-1(a)(2).

26. Finally, Congress did not direct that the Secretary should collect private payor data from principally the two largest, national clinical laboratories. The Secretary must know that these two laboratories have negotiated many exclusive or preferred provider agreements with commercial and managed care payors, by offering reduced rates. Those laboratories are not representative of the industry as a whole, nor are the rates that they receive representative of the rates paid to hospital laboratories, or other independent laboratories.

I declare that the foregoing is true and accurate, to the best of my knowledge, under penalties of perjury.

DATED: February 19, 2018

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.

EXHIBIT A
TO
DECLARATION OF MARK S. BIRENBAUM, PH.D.

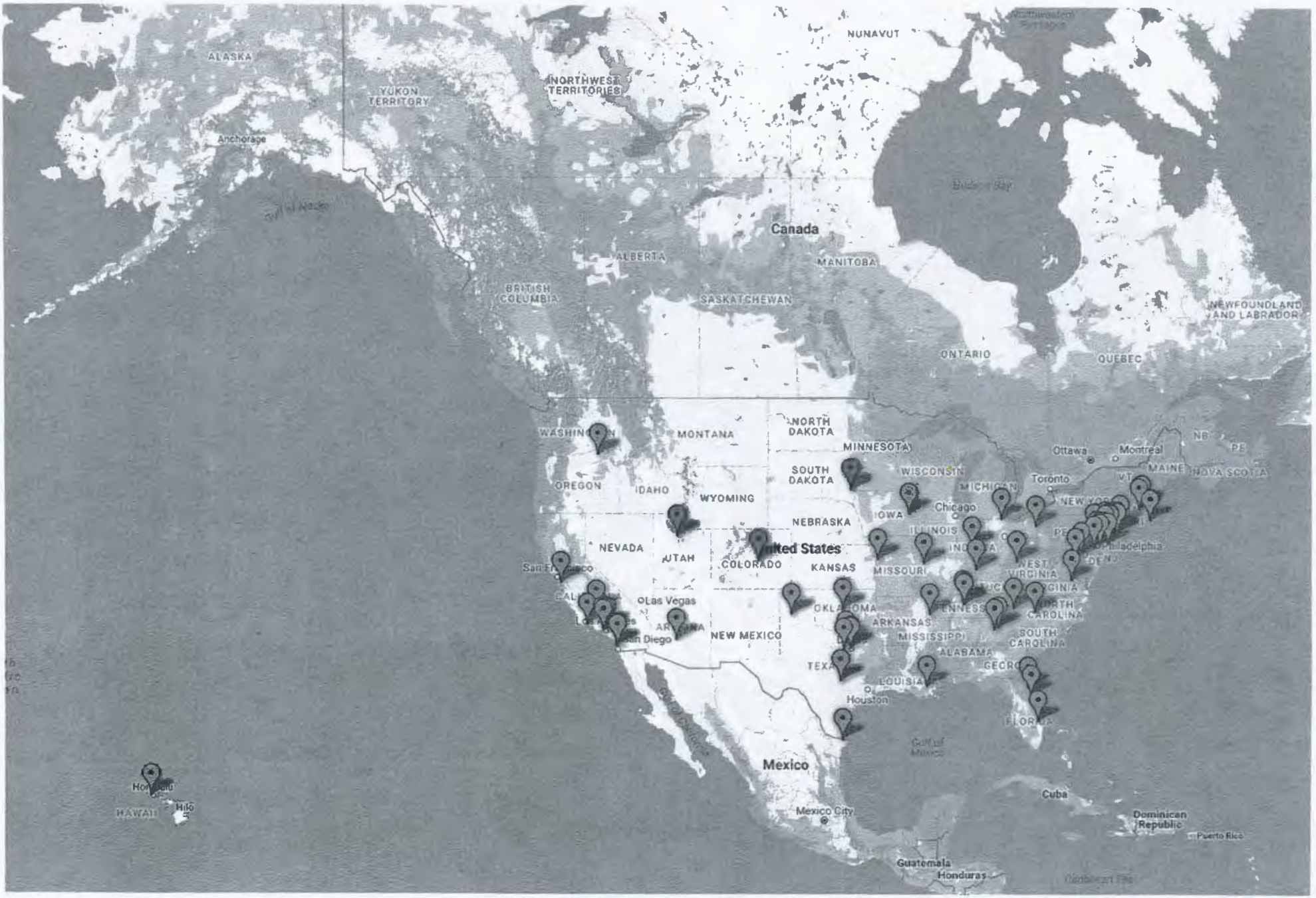
NUNAVUT
ALASKA
YUKON TERRITORY
NORTHWEST TERRITORIES
Anchorage
Canada
ALBERTA
MANITOBA
BRITISH COLUMBIA
SASKATCHEWAN
NEWFOUNDLAND AND LABRADOR
ONTARIO
QUEBEC
NORTH DAKOTA
MONTANA
MINNESOTA
Ottawa
Montreal
SOUTH DAKOTA
WISCONSIN
MAINE
NOVA SCOTIA
Toronto
OREGON
IDAHO
WYOMING
MICHIGAN
Chicago
IOWA
NEBRASKA
NEVADA
UTAH
COLORADO
KANSAS
MISSOURI
WEST VIRGINIA
Las Vegas
OKLAHOMA
ARKANSAS
NEW MEXICO
MISSISSIPPI
SOUTH CAROLINA
ALABAMA
TEXAS
LOUISIANA
Houston
Mexico
Cuba
HAWAII
Hilo
Mexico City
Dominican Republic
Puerto Rico
Guatemala
Honduras

EXHIBIT B

TO

BRIEF OF AMICUS CURIAE AMERICAN ASSOCIATION OF BIOANALYSTS

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR, II, In His Official Capacity as Secretary of Health and Human Services, U.S. Department of Health and Human Services Defendant.	Civil Action No.: 1:17-cv-02645-EGS

DECLARATION OF ANNETTE IACONO

I, Annette Iacono, declare the following to be true and correct to the best of my knowledge:

1. I am a resident of Delaware County, Pennsylvania. I am over the age of eighteen and am competent to provide this Declaration.

2. I am Vice-President of Brookside Clinical Laboratory, Inc. ("Brookside") located in Aston, PA 19014. As representative of Brookside, I have been a member of the American Association of Bioanalysts ("AAB") since 1994. I have also served on AAB's Board of Directors from 1999 to present. I submit this Declaration as part of the application of AAB to file papers as an Amicus Curiae in support of the Complaint filed by the American Clinical Laboratory Association, and as part of its proposed Amicus Brief.

3. Brookside was formed in 1966 by my father and it remains a family business. My father, my sister, my niece and I all work at Brookside.

4. Brookside currently employs 86 people, approximately 95% of whom are women or minorities. The average tenure of our employees is 30 years, and for several, Brookside is the only employer they have ever had.

5. Given my life-long experience with Brookside and the family operations, I am intimately familiar with the business, its employees and the customers we serve, as well as the changes that the laboratory industry has faced over the last several decades. The purpose of this Declaration is to show why Congress could not have intended to create the vacuum of laboratory services available to nursing home residents that will occur if the definition of "applicable laboratory" in the PAMA regulations continues in effect.

6. Brookside meets a special need in the community. Ninety percent of our business is derived from serving patients in long-term care facilities, particularly nursing homes. We service approximately 90 nursing homes, some for as many as 40 years. In 2017, Brookside performed approximately 598,817 tests for the residents in nursing homes. One particular nursing home has nine hundred beds.

7. The continued viability of Brookside is critical, not just to our employees, but to the nursing home population as well. We are one of the only laboratories in an approximately 100-mile radius that performs such testing for long-term care facilities. A principal reason for this is that the large independent laboratories typically do not service nursing homes. Labor costs are too high, profit margins are too low, and facilities tend to be too scattered, particularly in rural areas.

8. Patients in nursing homes cannot travel. They are medically fragile and nursing homes do not have their own in-house laboratories. It is therefore necessary for the

laboratory to come to them. As a matter of necessity, nursing homes must rely exclusively on outside laboratories to provide clinical laboratory services.

9. Due to the complex and chronic conditions of residents, we send phlebotomists on a daily basis to these facilities to collect specimens, return the specimens to the laboratory and report same-day results to the provider. To accomplish this, Brookside limits its service area to an approximately 100-mile radius. Further, the medical need for immediate test results for such medically fragile patients is sufficiently urgent that Brookside has stayed open and has continued to provide services regardless of weather conditions. In years past, we have stayed open, collected specimens, conducted laboratory tests and reported results to client nursing homes even in blizzard conditions that caused many other businesses to close.

10. The intensity of services a laboratory like Brookside must provide to nursing homes is also unique. As part of the normal day, Brookside sends phlebotomists for blood draws to the nursing homes as early as 5:00 am. The phlebotomists must wake up the residents and sometimes engage with them to get their blood drawn. Oftentimes, the residents at the facility also require special care because it is more difficult to draw blood from elderly and disabled residents, due to their age, physical conditions or mental status. Brookside finds it more effective and productive to send the same phlebotomists as often as possible to the same nursing home because the residents are more willing to have their blood drawn by a familiar face.

11. Brookside provides a twenty-four hour turnaround time for its test results, including for prothrombin time (PT) testing (to detect and diagnose a bleeding or excessive clotting disorder). In addition, Brookside provides 'STAT' testing when the urgency of the situation demands immediate test results. Many of these tests performed by Brookside yield

the lowest reimbursement rates by Medicare but are the essential tests for residents of skilled nursing facilities.

12. Brookside also performs rapid influenza tests and provides results within hours of having the specimens arrive at the laboratory. Recently, I was called on a Sunday by a director of nursing at one of the skilled nursing facilities that had an influenza outbreak. She was calling to inform me that she would need blood draws for seventy-one patients for a rapid influenza test the next day in order to determine who would need Tamiflu. We sent two phlebotomists to the nursing home and provided results within hours of the specimens being back at the laboratory. It was critical that we provided those results because of the devastating impact influenza can have in the elderly population, particularly with some being so medically compromised. Antiviral treatment, such as Tamiflu, is best administered within forty-eight hours, so the facility needed a quick turnaround on results.

13. Brookside has also historically provided another critical service to a population not met by the larger national laboratories or hospital-based laboratories – house calls to homebound patients. It is not uncommon for elderly, sick or disabled individuals to be homebound, but who are in need of blood draws for laboratory tests ordered by their physicians. Again, these are individuals who are in need of important testing, such as PT/INR tests to ensure that their blood is clotting correctly. These tests are important when individuals are taking medicines such as Coumadin, which is used to treat or prevent blood clots. These individuals are unable to travel, and similar to those residents in a skilled nursing facilities, are dependent upon phlebotomists coming to their homes to draw their blood. There is a dearth of laboratories that will perform these home draws, particularly away from more heavily populated areas.

14. Now that the Court understands the patients who rely upon Brookside, and the services we provide, it is important to explain how the definition adopted by the United States Department of Health and Human Services ("HHS") of the term "applicable laboratory" will affect not only Brookside, but also the communities we serve.

15. Approximately eighty-five percent of Brookside's revenue is from Medicare, whether Part A or Part B. For residents covered under Part B, Brookside will bill Medicare directly. Otherwise, for in-patient beneficiaries being covered under Part A of Medicare, the nursing home bills Medicare a global rate and Brookside bills the nursing home pursuant to a negotiated rate. Overall, Brookside's profit margin is less than 5%. While this is very low, it is consistent with the profit margins experienced by other laboratories in the nursing home business. It is the primary reason why so few laboratories elect to service this population.

16. Due to the fact that Brookside predominantly serves long-term care facilities and also homebound patients, and its revenue is tied directly to Medicare reimbursement, section 216 of the Protecting Access to Medicare Act (PAMA) of 2014 will have a significant impact on the services we can continue to provide.

17. PAMA was designed to provide the Secretary with information about the market as a whole that would accurately represent the commercial rates paid by private payors to clinical laboratories. Yet, the Secretary's final ruling implementing PAMA appears to have been purposefully designed in such a way as to deprive the Secretary of information Congress required from all of the laboratories that participate in the market and, as a result, the information is not representative of the market.

18. Congress instructed the Secretary of HHS to collect data from all laboratories that receive a majority of their Medicare revenues from the clinical laboratory or physician fee

schedules. I understand that a major problem with the final rule lies in the definition used by HHS for "applicable laboratory." The result, as I understand, is that virtually the only rates reported to HHS were from a small number of independent clinical laboratories, particularly Quest Diagnostics and LabCorp. HHS' definition of "applicable laboratory" excludes almost all hospital laboratories and, as a result, the Secretary has failed to collect information about the commercial rates they receive from private payors.

19. The current implementation, which is not reflective of Congress' directive, will have a severe impact on Brookside. Because HHS has not collected information from the market as a whole, it does not have the information it needs to establish rates for the Clinical Laboratory Fee Schedule that reflect market rates. As a result, if HHS's final rule is not revised and corrected, the rates under the Clinical Laboratory Fee Schedule will continue to contravene Congress' intent and will be artificially depressed. If no correction is made, Brookside will simply not be able to afford to continue operating in its current mode. It will be forced to make difficult decisions including reducing or eliminating service to some of its skilled nursing facility clients and laying off employees. If the new PAMA rates continue because of the exclusion of hospital laboratories, based upon the improper definition of "applicable laboratory," Brookside will be forced to close its doors in the next few years, ending a family business of three generations that serves a vital need in its community.

20. Since Brookside is already one of the only clinical laboratories servicing nursing home clients and homebound patients in our community, and rates will go down further due to the improper exclusion of hospital laboratories, it is apparent that there will be a problem of access to laboratory testing. We have already had to make the decision that we cannot afford to continue making home visits to homebound patients, and have started notifying our

physicians. I do not know what laboratories will step into these breaches when Brookside cannot service nursing home and homebound patients. The nursing homes may be forced to take their residents to the hospital by transport for 'STAT' testing, which will increase costs to the facility as well as pose potential harm to the residents, including risk of infection in those already medically compromised. In addition, the nursing homes will not be able to get results within hours as they do now because the infrastructure will not be there to support the collection and turnaround times provided by Brookside. I also do not know what will happen with homebound patients. This delay in reporting laboratory results will have a direct impact on treatment decisions and outcomes. It is my understanding that approximately 70% of physician treatment decisions are driven by laboratory testing.

21. As a member of AAB, I interact with clinical laboratories all over the country almost daily and I have done so for many years. At meetings and in normal day-to-day discussions with other nursing home laboratories, I am very much aware that the problems caused by HHS' implementation of PAMA, with the purposeful exclusion of hospitals, will not be limited to Brookside, but will be experienced by all laboratories servicing nursing homes. For the reasons I described above, the labor costs of servicing nursing homes is very high. Medicare reimbursement, however, was already low, so that the draconian cuts resulting from HHS' failure to comply with the PAMA statute, by excluding higher hospital reimbursement data from the data HHS collected, will necessarily bring rates below cost, or mandate severe restrictions in services.

22. I do not believe that Congress could have intended this result, since the purpose of Medicare is to increase access to health care for the aged and disabled, not to deprive the most vulnerable population of needed laboratory services. The purpose of the PAMA statute

enacted by Congress was to get a true and comprehensive picture of the rates paid in the entire market of commercial payors. By adopting a definition of "applicable laboratory" that excludes hospital laboratories and others, CMS has defeated that design, and will cause major disruptions in the provision of laboratory services.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, to the best of my knowledge.

Dated: 02/18/18

Annette Iacono

EXHIBIT C

TO

BRIEF OF AMICUS CURIAE AMERICAN ASSOCIATION OF BIOANALYSTS

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR, II, In His Official Capacity as Secretary of Health and Human Services, U.S. Department of Health and Human Services Defendant.	Civil Action No.: 1:17-cv-02645-EGS

DECLARATION OF THOMAS KENNEDY

I, Thomas Kennedy, declare the following to be true and correct to the best of my knowledge:

1. I am a resident of Umatilla County, Oregon. I am over the age of eighteen and I am competent to provide this Declaration.

2. I am owner/President and CEO of Interpath Laboratory, Inc. ("Interpath") located in Pendleton, Oregon 97801. Interpath is a member of the American Association of Bioanalysts ("AAB") and provides representation on the current AAB Board of Directors.

3. Interpath was formed in 1967 and celebrated 50 years of service to the Pacific Northwest in 2017. The laboratory was originally founded by a local pathologist, and my wife and I purchased the business in 1989. Three of our four sons and a third generation granddaughter are also heavily involved in the business.

4. Our business model was created to provide a high level of service to our physician clientele enhancing their ability to diagnose, treat and monitor their patients. Unlike the large

national laboratories, we understand that healthcare is local and time is critical; thus we have over 60 patient service centers throughout the states of Washington, Oregon, Idaho, Nevada and Alaska. Of those 60 sites, 46 sites offer waived testing with 26 offering moderate to high complexity laboratory testing. Waived, moderate and high complexity are different levels of testing under the Clinical Laboratory Improvement Amendments of 1988, which is a federal law that sets quality control, personnel and other standards for every site in the country where any clinical laboratory testing is performed. This model of local, scattered patient service centers, with different test offerings, allows our laboratory to provide results to our physicians within hours of collection, giving providers results that can help them quickly diagnose and manage critical disease states.

5. Our staff numbers 747 employees throughout our five-state market area that serve physicians, clinics, hospitals, nursing homes, prison systems, and Indigent Care Clinics. Thirty-eight percent of our business is reimbursed directly from Medicare or state Medicaid plans, with the remaining reimbursed by third-party commercial payers. The majority of those third-party commercial payer rates are set by the insurers at a percentage of Medicare. Basically 82% of our reimbursement is tied to the Clinical Laboratory Fee Schedule. If Medicare rates go down, these commercial rates will go down.

6. Because our business is healthcare, each and every test or service we provide could potentially be life changing for the patients we serve. We take this responsibility seriously and many times go beyond normal service levels to meet individual patient and physician needs. One area that differentiates Interpath from other laboratories is our courier system which is wholly owned and staffed by Interpath employees. Monday through Friday, our courier system travels over 10,000 miles each day to retrieve and deliver specimens to the testing facilities. We encounter mountainous terrain with 5 major summits that are traversed daily and in some locations twice a

day. This can present major difficulties with the extreme weather conditions we experience in the Pacific Northwest. For example, one day in February 2017 when the US Postal Service, UPS and Fedex trucks were all sidelined due to weather, Interpath couriers accomplished all of their routes to collect specimens.

7. Much of our market encompasses truly rural and remote locations, and this fact requires our couriers to know more than just how to pick up a specimen. Many times our couriers detect problems with specimen types and temperatures at the facilities before leaving and can correct mistakes that would otherwise delay results. There are no other laboratories that maintain an intricate courier system throughout our market area using employees specifically trained in laboratory services. The problem, however, with attracting clinical laboratory services to these rural areas is largely due to heavy labor costs associated with the travel, on-site phlebotomy and rapid processing. A laboratory willing to provide services is crucial to the treating physicians, but hard to find. Without local laboratories willing to partner with physicians, patients will lose access to the medical care they deserve. The final rule implemented by the Secretary will lead to even less attraction in these rural markets and a dearth of services.

8. Interpath provides knowledgeable laboratory representatives who schedule routine visits to all clients to provide assistance and solutions related to laboratory issues. Our representatives bring valuable laboratory expertise and help physicians understand new and complex testing. We also provide training to clinic staff. Providers in all areas, even in metropolitan communities, cannot keep up with the constantly evolving laboratory landscape. As more esoteric and highly technical testing is being developed, our job is to help physicians understand the efficacy of such testing and to assist providers in knowing how and what to order.

9. The Community Health Clinics are another client group that is becoming more

prevalent in our market area. They provide healthcare services to indigent and low-income patients. Patients are charged on a sliding scale based on their income and the Federal Poverty Level. Laboratories are expected to charge those uninsured patients on the same sliding scale. Since these clinics are located in rural communities, again few laboratories are willing to spend the resources to provide services. While the Federal government is working hard to keep these clinics open and accessible, including ongoing funding, the Secretary of Health and Human Services ("HHS") seems to be working in the opposite direction by knowingly applying the Protecting Access to Medicare Act ("PAMA") statute in a way that will force laboratories like Interpath to terminate or reduce not only Medicare beneficiary access to services, but other patients as well.

10. Interpath also provides laboratory services to community hospitals. It is not uncommon for us to share reagents or perform testing for our hospital clients when their equipment is down or they run out of reagent. We also assist them with correlations to determine the accuracy of their equipment. Small rural hospitals have difficulty hiring and keeping qualified personnel, so Interpath has provided managerial support and oversight numerous times in the past. Many Interpath trained technologists work in these hospital settings.

11. Interpath has also provided nursing home facilities with laboratory services since its inception. We currently list 187 nursing homes as clients. Because this element of healthcare is labor intensive, there are no other laboratories in many of the smaller communities that are willing to expend resources for the low reimbursement that accompanies a nursing home account.

12. These nursing homes almost never have an in-house laboratory and rely on the local, regional laboratory to provide services to these patients who cannot travel. We send phlebotomists daily to these facilities, starting as early as 5 am, to collect specimens, return the

specimens to the laboratory and report same day results to the provider. Our nursing home clients rely on us to provide these services so that they can treat the complex and chronic conditions of their residents. Our couriers, as noted above, are not sidelined by weather but continue to provide these vital services without delay.

13. As mentioned above, more than 82% of our revenue is directly tied to Medicare reimbursement. Medicare rates, however, do not just affect Medicare beneficiaries. These same rates drive what commercial insurance payers, like Blue Cross or Blue Shield plans, or major insurers like Aetna and Cigna, are willing to pay. There is a common misperception that laboratories like Interpath are able to negotiate rates with commercial payers for network contracts. The reality is that commercial payers have a "take it or leave it" approach, and we are forced to accept their reimbursement. The implementation by the Secretary of section 216 of PAMA will therefore create a reimbursement system that spirals downward much more than Congress could have ever intended.

14. The failure by the Secretary to collect information from all of the laboratories that participate in the market, and the Secretary's knowing exclusion of a major portion of the laboratory market, i.e. hospital laboratories, is inconsistent with and defeats the purpose of PAMA, which was to provide the Secretary with information about the market as a whole that would accurately represent the commercial rates paid by private payers to clinical laboratories and to promote access to care for the aged and disabled.

15. The major problem as I understand it, lies in the definition used by the Secretary for 'applicable laboratory.' The definition, which relies upon a laboratory having a National Provider Identifier ("NPI"), excludes almost all hospital laboratories and therefore has excluded a major part of the market. As a result, the data collected under the final rule does not reflect all the

commercial rates that laboratories receive from private payers and is in contravention of the intent of Congress in passing PAMA. It creates false market rates.

16. If no correction is made, Interpath will be forced to make difficult decisions, including reducing or eliminating service to some of its clients, particularly those facilities in more rural areas that already have little to no other options for laboratory services. Interpath may also be forced to close its doors in the next few years, ending a family business of three generations that has served the vital needs of its communities for the past 50 years. Already, we will be reducing our workforce effective March 1, 2018, reducing our hours in our patient service centers and eliminating some of our courier routes. These changes will eliminate same day results and restrict the service areas and ability to provide STAT services for some nursing home clients.

17. As a member of AAB, I interact with clinical laboratories all over the country. I am very aware of the problems caused by the implementation of the final rule due to my discussions at meetings, including a recent meeting held in San Diego by a division of AAB called the National Independent Laboratory Association ("NILA"), and in normal day-to-day discussions with other laboratories. It is evident from my own experience and from discussions with other laboratories that the large "Wall Street" national independent laboratories have traditionally not provided services to rural areas because of the lower profit margin and courier requirements, and they will not begin to do so now. Regional laboratories like Interpath serve these populations. We have learned, however, that the Secretary's implementation of PAMA will not only cause Interpath, but other laboratories as well, to severely reduce or eliminate services to rural communities. Local hospital laboratories in those communities have not developed the infrastructure that we and other regional laboratories have developed to provide the necessary services, and they are not equipped at this time to do so. This will affect not only Medicare

beneficiaries, but all patients in hard-to-reach rural and outlying communities.

18. I do not believe that Congress could have intended this result. The purpose of PAMA was to perform a true market study and see whether Medicare payments were reflective of the commercial payer market in order to promote access to health care for the aged and disabled, not to deprive these individuals of necessary laboratory services. The final rule, which adopts a definition of 'applicable laboratory' that is based on an NPI number and excludes hospital laboratories and others, will cause major disruptions in the provision of laboratory services.

I declare that the foregoing is true and accurate, to the best of my knowledge, under penalties of perjury.

Dated: 2-20-2018

Thomas Kennedy