IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION,
1100 New York Avenue, N.W., Suite 725W
Washington, D.C. 20005

Plaintiff,

v.

ERIC D. HARGAN,
In His Official Capacity as Acting Secretary of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Defendant.

Civil Action No. 1:17-cv-2645

COMPLAINT

Plaintiff American Clinical Laboratory Association ("ACLA") brings this lawsuit against the Acting Secretary of the United States Department of Health and Human Services ("Secretary") to challenge his unlawful disregard and violation of Congress's statutory directives in a final rule purporting to implement the data-reporting requirements of Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), Pub. L. No. 113-93, § 216, 128 Stat. 1040, 1053 (2014). *See* 81 Fed. Reg. 41,035 (June 23, 2016). Acting on behalf of its members, ACLA seeks declaratory and injunctive relief (1) requiring the Secretary to comply with the statutory requirements and (2) setting aside the provisions in the final rule that unlawfully exempt thousands of laboratories from the reporting obligations that Congress imposed. As grounds for this complaint, ACLA states as follows:

PRELIMINARY STATEMENT

1. Clinical laboratory services are tests performed on specimens from the body, such as blood or urine, that are used to monitor, diagnose, and treat patients. The laboratories that perform these services, from routine blood tests to ground-breaking genetic and molecular tests, play a vital role in the nation's health care system. The Centers for Medicare & Medicaid Services ("CMS"), through the Medicare program, is the nation's single largest purchaser of clinical laboratory services.

2. In 2014, Congress enacted Section 216 of PAMA to modernize the way in which the Medicare program reimburses laboratories for the services they provide. A central feature of PAMA is Congress's direction that laboratories must report market information to the Secretary so the Secretary can ensure that Medicare reimbursement rates more closely reflect the rates laboratories receive from private payors. ACLA was a strong supporter of Congress's market-based reforms, which resulted in the most extensive changes to the system for reimbursing clinical laboratories since 1984.

3. Section 216(a) of PAMA, which is codified at 42 U.S.C. § 1395m-1, includes two separate provisions. *First*, subsection (a) mandates that all "applicable laboratories" report private payor market pricing information to the Secretary. *See* 42 U.S.C. § 1395m-1(a). The statute directs the Secretary to promulgate judicially reviewable regulations setting the parameters for reporting data, requires that the collected data be held in confidence, and authorizes the Secretary to impose civil monetary penalties on any laboratory that fails to report. *Second*, subsection (b) instructs the Secretary to take the reported information collected from all applicable laboratories and to use it to establish new Medicare reimbursement rates for clinical laboratory services. *See* 42 U.S.C. § 1395m-1(b).

4. This complaint addresses the first of these provisions. It challenges the Secretary's final regulations promulgated under 42 U.S.C. § 1395m-1(a), which disregard and violate the statute's specific, unambiguous directives requiring that all applicable laboratories report relevant data to the Secretary.

5. In imposing these requirements, Congress took care to specify which laboratories would be obligated to report market data to ensure that information would be collected from a broad, diverse group of market participants. Congress made clear that any "laboratory" would be required to report data if, "with respect to its revenues under [the Medicare program], a majority of such revenues are from" the Physician Fee Schedule or the Clinical Laboratory Fee Schedule. 42 U.S.C. § 1395m-1(a)(2). Accordingly, under the statute, all laboratories that receive a majority of their Medicare revenues from these fee schedules must report market data, a result that is consistent with Congress's decision to ensure that Medicare rates are set consistent with market forces.

6. In promulgating his regulations, however, the Secretary disregarded Congress's express instructions and unreasonably and arbitrarily exempted significant categories and large numbers of laboratories that meet the statutory definition from the reporting requirements that Congress imposed. The Secretary's final rule fatally undermines one of PAMA's purposes, which is to require a broad spectrum of Medicare-participating laboratories to report market information to the Secretary. Instead, in *ultra vires* fashion, the Secretary has carved out large categories of laboratories — ultimately resulting in the exclusion of some 99.3 percent of the laboratory market — from the statutory reporting requirements.

7. Although there are more than 261,500 unique entities that received Medicare payment for laboratory services in 2015, only 1,942 laboratories reported information in 2016

pursuant to the Secretary's final rule — approximately 0.7 percent of the total number of laboratories that currently serve Medicare beneficiaries. Moreover, contrary to Congress's intent, the laboratories that did report information are not representative of the market as a whole. For example, although approximately 7,000 hospital laboratories billed Medicare for laboratory services in 2015 — accounting for 24 percent of the Medicare payments made under the Clinical Laboratory Fee Schedule — no more than 21 hospital laboratories (and probably even fewer) reported information to the Secretary, leaving hospital laboratories effectively unrepresented in the data collected by the Secretary. Hospital laboratories are often the only laboratories available to patients in certain areas of the country, and the private payor rates they receive are often much higher than other laboratories, due to differences in competitive markets, volumes of services, and other factors. *See* Declaration of John Kolozsvary ¶ 16 (included as Attachment B); *see also* Declaration of Dermot Shorten ¶ 14 (included as Attachment C).

8. The vast majority of the data collected by the Secretary was collected only from the nation's two largest, independent laboratories, which are located predominantly in large, urban areas, and have much lower cost structures. *See* Shorten Decl. ¶¶ 11–12. In short, instead of collecting data from the market as a whole, as Congress required, the Secretary has implemented the statutory reporting requirements in a way that cherry-picks data from only a small portion of the market that overall receives the lowest private payor rates. The Secretary is aware of this fact and has analyzed the extent to which this cherry-picked data lowers Medicare payment rates. *See* "Hidden Data" tab in CY 2018 Final Private Payor Rate-Based CLFS Payment Rates, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

9. Because the information reported to the Secretary does not reflect the market as a whole and does not comply with Congress's directives, any Medicare rates that are later set using the reported information will not meet the standard that Congress intended. Indeed, by excluding virtually all hospital laboratories from the statutory reporting requirements and by relying instead on non-representative data from the nation's two largest independent laboratories, the Secretary has ensured that Medicare rates will not be consistent with market-based rates and will be much lower than Congress intended. *See* Kolozsvary Decl. ¶ 26; *see also* Shorten Decl. ¶¶ 14–15.

10. This unlawful failure to implement Congress's commands may benefit the Secretary's short-term interests in reducing Medicare costs and making the data-collection process easier for the Secretary, but the consequences are severe and disastrous for everyone else. If the Secretary's failure to comply with Congress's directives is not corrected, laboratories will be forced to stop providing essential services, especially in remote rural areas, and many laboratories will be forced out of business. Kolozsvary Decl. ¶ 27; *see also* Declaration of Peter Gudaitis ¶¶ 22–24 (included as Attachment A). Beneficiaries may be unable to obtain essential laboratory testing services, especially sick and elderly patients in nursing home facilities who depend on laboratory testing services. Gudaitis Decl. ¶¶ 28–31. The result will be to dramatically decrease available services and the quality of care. *See* Kolozsvary Decl. ¶ 27; Gudaitis Decl. ¶¶ 28-31; Shorten Decl. ¶¶ 18–19. In short, contrary to Congress's intent, instead of reforming Medicare reimbursement rates to more closely reflect the market, the Secretary's final rule will disrupt the market and prevent beneficiaries from having access to the essential laboratory services they need.

11. The Secretary's final rule contravenes the plain language of PAMA Section 216(a) as codified at 42 U.S.C. § 1395m-1(a), is an impermissible and unreasonable

interpretation of Section 216(a) as codified at 42 U.S.C. § 1395m-1(a), and is arbitrary and capricious under the Administrative Procedure Act ("APA"), 5 U.S.C. § 500, *et seq.* It should therefore be vacated.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 to review the Secretary's final rule because ACLA's causes of action arise under the laws of the United States, including under PAMA and the APA, 5 U.S.C. § 702.

13. In the alternative, this Court has jurisdiction under 42 U.S.C. § 405(g) of the Medicare statute. ACLA and its membership have presented their claims to the Secretary and the Secretary has denied relief for these claims.

14. There is no administrative appeals process by which ACLA could seek further administrative review of its claims. Numerous commenters, including ACLA, objected to the Secretary's final rule because it impermissibly and unreasonably exempts a large number of laboratories from the statutory reporting requirements that Congress imposed. ACLA and its membership met with representatives from CMS on numerous occasions, both before and after the Secretary promulgated the regulations, to present their claim that the final rule is arbitrary, capricious, and in excess of statutory authority. *See* Declaration of Julie Khani ¶ 12 (included as Attachment D). The Secretary has refused to reconsider the final rule or to take any other steps to comply with Congress's directives.

15. ACLA has exhausted all the administrative remedies that are available to it, and its only potential recourse is through judicial review of the Secretary's final rule.

16. Venue is proper under 28 U.S.C. § 1391(b), because the defendant, in his official capacity as Acting Secretary of the United States Department of Health and Human Services resides in or performs his official duties in this judicial district, and because a substantial part of

the events giving rise to this action occurred in this judicial district. Venue is also proper under 42 U.S.C. § 405(g) because ACLA resides in and has its principal place of business in the District of Columbia.

17. ACLA has standing to bring this lawsuit. ACLA actively participated in the rulemaking proceedings and has a substantial interest in ensuring that the Secretary's regulations comply with statutory mandates and that regulatory burdens are imposed in an even-handed manner, as Congress intended. In addition, at least one of ACLA's members has been injured by the Secretary's final rule and has standing to sue in its own right, the interests ACLA seeks to protect are germane with its purpose, and ACLA's members are not required to participate in this lawsuit in order to obtain relief against the Secretary.

PARTIES

18. ACLA is a not-for-profit association with its principal place of business in Washington, D.C. ACLA represents the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. ACLA's members perform millions of tests each year for patients that are reimbursed under the Medicare program.

19. Defendant Eric D. Hargan is Acting Secretary of the Department of Health and Human Services and is sued in his official capacity. The Department of Health and Human Services is the federal agency that administers CMS. CMS is the federal agency to which the Secretary has delegated administrative authority over the Medicare program. References to the Secretary herein are meant to refer to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires. The Secretary oversees regulation of laboratories under the Medicare program, including those actions complained of herein.

GENERAL ALLEGATIONS

A. Medicare Coverage of Clinical Laboratory Services

20. The Medicare program provides federally funded health insurance for certain elderly and disabled persons under title XVIII of the Social Security Act. 42 U.S.C. § 1395.

21. Part A of the Medicare program covers payment for inpatient hospital services and post-hospital extended care in an institutional setting. 42 U.S.C. § 1395d(a)(1)-(2). Part B covers payment for medical and other health services, including clinical diagnostic laboratory services. 42 U.S.C. § 1395k(a)(1); 42 U.S.C. § 1395x(s).

22. Laboratories that provide clinical diagnostic services to Medicare beneficiaries are located in a wide variety of settings, including in hospitals (which furnish services to both inpatients and outpatients of the hospital as well as to non-patients, *i.e.*, patients who see their physicians in their offices but whose specimens are tested at a hospital), physician offices and skilled nursing facilities. Beneficiaries also often receive clinical diagnostic services from "independent laboratories," which, as the name implies, are not affiliated with another health care provider.

23. Laboratories must operate within a strict set of regulatory parameters in order to receive Medicare reimbursement. Part B only "pays for covered diagnostic laboratory services" provided by "[a] laboratory, if it meets the applicable requirements . . . of part 493 of this chapter. . . ." 42 C.F.R. § 410.32(d)(1)(v). Part 493 is a reference to the regulations that implement the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). *See* Pub. L. No. 100-578, 102 Stat. 2903 (1988), codified at 42 U.S.C. § 263a. A bedrock principle of Medicare reimbursement is that a laboratory must be certified under the CLIA regulations in order to bill Medicare for its services. In other words, as Congress would have recognized when it enacted PAMA, all laboratories that receive payments from Medicare are easily identified as

"laboratories" under the existing regulatory scheme by their CLIA certification number, which they are required to have and maintain.

24. The setting in which Medicare beneficiaries receive clinical diagnostic laboratory services determines how the Medicare program provides reimbursement. The Medicare program distinguishes between, on one hand, beneficiaries that have laboratory tests performed as part of a registered hospital visit and, on the other hand, beneficiaries that have the tests performed separate from and not in connection with any registered hospital visit.

25. For registered hospital inpatients (patients who are admitted to the hospital with a physician order), payment for clinical diagnostic laboratory services is typically bundled into the payment that hospitals receive upon discharge for inpatient services under the Inpatient Prospective Payment System. 42 U.S.C. § 1395ww(d). For registered hospital outpatients (patients receiving services who have not been formally admitted to the hospital), payment for clinical diagnostic laboratory services is generally bundled into the payment that hospitals receive for related outpatient services under the Outpatient Prospective Payment System. 42 U.S.C. § 1395l(t); 81 Fed. Reg. 79,562, 79,592–93 (Nov. 14, 2016).

26. Medicare beneficiaries also often require clinical diagnostic laboratory services when they are not registered as inpatients or outpatients of a hospital. That often happens, for example, when a beneficiary visits her doctor and is told to go to a laboratory to have certain tests performed. When clinical laboratory services are provided in this way, Medicare Part B typically pays for the services based on the Clinical Laboratory Fee Schedule. 42 U.S.C. § 1395l(h)(1)(B). That fee schedule applies regardless of whether the laboratory the beneficiary chooses is independent or operated by a hospital.

27. Hospital laboratories that provide clinical laboratory services to Medicare beneficiaries who are not registered inpatients or outpatients of the hospital are commonly referred to as "hospital outreach laboratories." Although they are affiliated with a hospital, they compete with and provide the same clinical services to the local communities that are provided by other laboratories. *See, e.g.*, Medicare Claims Processing Manual (Pub. No. 100-04), Ch. 16, § 10 ("When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory . . . .").

28. Hospital outreach laboratories make up a substantial part of the market, serving a large number of private payor patients and Medicare beneficiaries. In terms of Medicare spending, hospital outreach laboratories received approximately 26 percent of the payments made under Medicare's Clinical Laboratory Fee Schedule in 2016. *See* Office of Inspector General ("OIG"), Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data, OEI-09-16-0004 (Sept. 2017), at 2, *available at* https://oig.hhs.gov/oei/reports/oei-09-17-00140.pdf ("OIG 2016 Data Report"). By comparison, independent laboratories and physician office laboratories account for approximately 55 percent and 18 percent of Clinical Laboratory Fee Schedule payments, respectively. *Id.*

29. Before PAMA, clinical laboratory services were reimbursed at the lesser of either (1) the laboratory's charge or (2) the local amount under the Clinical Laboratory Fee Schedule, which varied based on a "regional, statewide, or carrier service area basis" and was subject to a national limit. 42 U.S.C. § 1395l(a)(1)(D)(i)(I); *see also* 42 U.S.C. §§ 1395l(h)(1)(C), (h)(4)(B). This system, which Congress required the Secretary to establish in 1984, *see* Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2303(d), 98 Stat. 494, 1064 (1984), was heavily criticized because it imposed arbitrary local deviations in reimbursement amounts. The Clinical

Laboratory Fee Schedule also reimbursed laboratories at rates that were lower than their standard charges, and ignored market forces.

30. By 2007, 56 carrier localities existed, meaning that any given laboratory test could have 56 different payment amounts on the Clinical Laboratory Fee Schedule depending on where the testing occurred. *See* OIG, Variation in the Clinical Laboratory Fee Schedule, OEI-05-08-00400 (July 2009) at 1, *available at* https://oig.hhs.gov/oei/reports/oei-05-08-00400.pdf. In a study of 2007 claims data, the government found that variations in reimbursement amounts were not tied to geographic differences in wage costs or other factors, *id.* at 9, and "may not have reflected real differences in cost from carrier to carrier," *id.* at 11.

31. Against this backdrop, in 2014 Congress enacted Section 216 of PAMA. PAMA imposed new requirements on both laboratories and the Secretary, establishing a new system applicable to all laboratories billing to the Medicare program. *See* PAMA § 216, amending 42 U.S.C. § 1395m-1. The objective was to make the reimbursement system more uniform and more consistent with private markets. To accomplish that objective, PAMA's central feature is its carefully designed data-reporting obligations, which require laboratories to report market pricing information to the Secretary. Once that information is collected, PAMA then directs the Secretary to use that information to establish new market-based Medicare payment rates.

32. ***PAMA's Data-Reporting Requirements.*** Section 216(a) requires "applicable laboratories" to report "applicable information" to the Secretary. 42 U.S.C § 1395m-1(a)(1).

33. Congress defined "applicable laboratory" to include any laboratory that receives a majority of its Medicare revenues from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule.

> In this section, the term 'applicable laboratory' means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this

> section, section 1833(h), or section 1848. The Secretary may 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.

42 U.S.C. § 1395m-1(a)(2).

34. Congress granted the Secretary only limited discretion to exclude laboratories with a low-volume or low-expenditure threshold from the statutory reporting requirements. This discretion to exclude low-volume, low-expenditure laboratories is consistent with Congress's intent that reporting obligations would be imposed even-handedly on all significant market participants, so the data collected by the Secretary would provide a fair and accurate representation of the market as a whole.

35. As the legislative history confirms, Congress intended for "all sectors of the laboratory market [to] be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule." 160 Cong. Rec. S2860 (daily ed. May 8, 2014) (statement of Senator Richard Burr, affirmed by Senator Orrin Hatch).

36. Congress reinforced this directive by making clear that any laboratory that failed to meet its statutory reporting obligations could face civil penalties, in an amount of up to $10,000 per day for each failure to report. 42 U.S.C. § 1395m-1(a)(9)(A).

37. Because Congress was imposing new obligations on private laboratories to report commercial price information, it also ensured that the Secretary's actions implementing the statutory reporting requirements would be subject to judicial review. It instructed the Secretary to engage in public notice-and-comment rulemaking. Specifically, Congress directed that "[n]ot later than June 30, 2015, the Secretary shall establish through notice and comment rulemaking the parameters for data collection under this subsection." *Id.* § 1395m-1(a)(12).

38. ***PAMA's Rate-Setting Requirements.*** In addition to imposing obligations on laboratories to report market information, Congress separately instructed the Secretary how the information should be used to establish the updated rates. Congress directed the Secretary to calculate a weighted median "[f]or each laboratory test with respect to which information is reported." 42 U.S.C. § 1395m-1(b)(2). Congress also defined when the revised payment amounts would apply, *see id.* § 1395m-1(b)(4), directed how to make payment for new tests that are not advanced diagnostic laboratory tests, *see id.* § 1395m-1(d), and required that the Secretary consult with an expert outside advisory panel on establishing rates for new tests, *see id.* § 1395m-1(f).

39. Congress acknowledged that the new payment rates would likewise apply to hospital laboratories "if such test is paid for separately and not as part of a bundled payment under section 1833(t) [the OPPS]." 42 U.S.C. § 1395m-1(b)(1)(B). In other words, consistent with the current Clinical Laboratory Fee Schedule, Congress directed that the updated schedule would apply to non-hospital patients being treated in hospital outreach laboratories.

40. To afford the Secretary discretion in setting applicable rates, Congress prohibited either "administrative or judicial review" of "the establishment of payment amounts" for the reimbursement of clinical laboratory services. 42 U.S.C. § 1395m-1(h)(1).

B. The Secretary's Rulemaking

41. On October 1, 2015, the Secretary issued a proposed rule that would set parameters for the data-reporting obligations imposed on laboratories under 42 U.S.C. § 1395m-1(a). *See* 80 Fed. Reg. 59,386 (Oct. 1, 2015).

42. The Secretary's proposed rule rewrote the plain statutory requirements. Instead of collecting data from all "applicable" laboratories, as Congress directed, the Secretary proposed

that he would impose reporting obligations on only a very small subset of laboratory service providers.

43. In particular, instead of applying the statutory definition of "applicable laboratory" (any laboratory that receives the "majority" of its Medicare revenue from the Clinical Laboratory Fee Schedule or Physician Fee Schedule), the Secretary proposed to rewrite the definition of "applicable laboratory" to cover only those laboratories that have a unique taxpayer identification number ("TIN"). 80 Fed. Reg. at 59,392. The Secretary also solicited comments on defining "applicable laboratory" by reference to the National Provider Identifier ("NPI") the laboratory uses to bill its claims. *Id.* An NPI is a unique 10-digit number issued to health care providers by CMS that is used in transactions with commercial and government health plans, including the Medicare program.

44. In this way, the Secretary dramatically reduced the number of laboratories that qualify as "applicable laboratories," effectively exempting almost all hospital laboratories from the data-reporting obligations that Congress imposed. Both the NPI and TIN are almost always linked to the hospital itself — and not to the "hospital outreach laboratory." As a result, instead of looking at the revenues received from only the *laboratory*, the Secretary impermissibly and irrationally treated the entire hospital as a laboratory for purposes of evaluating whether the statutory revenue requirements are satisfied. As a result, because the hospital's overall Medicare revenues will almost always far exceed the revenues of the laboratory itself, the Secretary's statutory rewrite effectively carved out hospital laboratories from the statutory requirements and ensured that the statutory reporting obligations would be imposed primarily on only independent and physician-office laboratories. 80 Fed. Reg. at 59,393.

45. The Secretary received nearly 1,300 comments on his proposed rule. *See* https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=CMS-2015-0109&refD=CMS-2015-0109v-0002.

46. ACLA filed comments to the proposed rule, which are attached to the declaration submitted by ACLA's President, Julie Khani. *See* Khani Decl. ¶ 30, Ex. 14; *see also* https://www.regulations.gov/document?D=CMS-2015-0109-1113. ACLA objected to the Secretary's decision to exclude a large number of laboratories from the statutory reporting requirements, as a result of the Secretary's decision to define "applicable laboratory" based on each laboratory's NPI or TIN. ACLA "vehemently disagree[d] with CMS's inaccurate assumption that 'the statute intends to limit reporting primarily to independent laboratories and physician offices . . . and not include other entities (such as hospitals, or other health care providers). . . .'" Khani Decl. Ex. 14 at 4. To the contrary, "Congress intended that all sectors of the laboratory market . . . be represented . . ., including hospital outreach laboratories. If Congress meant to exclude all hospitals . . ., it easily could have done so directly, but it did not." *Id*.

47. ACLA objected in its comments that requiring reporting at either the TIN-level or NPI-level would exclude large numbers of relevant laboratories, because many hospital laboratories that derive a majority of their Medicare revenues from non-hospital patients would not clear the threshold imposed by the Secretary based on the hospital's entire Medicare revenue. *Id.* at 5.

48. As ACLA explained, "the agency would not be able to determine whether a majority of the *laboratory's* Medicare revenue is derived from" the Clinical Laboratory Fee Schedule or Physician Fee Schedule "as called for in the statute." *Id.* at 6 (emphasis original).

"[V]ery few hospital laboratories have laboratory-specific NPIs — even those with robust laboratory outreach programs — and they generally submit claims under the hospital's NPI." *Id.* at 5. As an alternative to TIN-level or NPI-level reporting, ACLA suggested that "applicable laboratory" be identified by CLIA certification number, which every laboratory is required to obtain and maintain in order to participate in Medicare. *Id.* at 6.

49. A wide variety of stakeholders raised similar objections to the Secretary's attempt to rewrite the statutory definition of "applicable laboratory" to exclude hospital laboratories from the reporting obligations that Congress imposed.

50. On June 23, 2016, the Secretary issued his final rule, but offered no meaningful response to the objections that had been raised. *See* 81 Fed. Reg. at 41,036.

51. In the final rule, the Secretary rewrote the definition of "applicable laboratory" so that it now reads:

> (1) Is a laboratory, as defined in § 493.2 of this chapter;
>
> (2) Bills Medicare Part B under its own [NPI];
>
> (3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period [from the Physician Fee Schedule or Clinical Laboratory Fee Schedule];
>
> 4) Receives at least $12,500 of its Medicare revenues [under the Clinical Laboratory Fee Schedule] . . ."

42 C.F.R. § 414.502. Subpart (1) is an explicit reference to the CLIA definition of laboratory at 42 C.F.R. § 493.2.

52. The Secretary's rule thus imposes a significant, additional requirement not found in the statute — that the laboratory separately bill Medicare "under its own [NPI]." Because almost all hospital laboratories that meet the statutory definition of an "applicable laboratory" do

not have their own NPI, the Secretary's rule impermissibly excludes laboratories that make up a substantial part of the laboratory market.

53. The Secretary's explanation for his final rule sharply contradicts his decision to rewrite the definition of "applicable laboratory." The Secretary repeatedly acknowledged the value of including a broad base of data reflective of underlying private payor rates. *See* 81 Fed. Reg. at 41,042 ("The [Clinical Laboratory Fee Schedule] applies to a wide variety of laboratories (for example, national chains, physician offices, hospital laboratories, etc.) and . . . it was important that we define laboratory broadly enough to encompass every laboratory type that is subject to the" Clinical Laboratory Fee Schedule); *id.* at 41,046 (noting the "advantage" of having "broader representation of the national laboratory market").

54. Nevertheless, the Secretary's revised definition excludes virtually all hospital laboratories from reporting data. *See* 81 Fed. Reg. at 41,045. In addition, the revised definition excludes approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories from reporting data. *Id.* at 41,051. The Secretary's response to these deficiencies — that "requir[ing] reporting by fewer entities . . . will be less burdensome to the laboratory industry," 81 Fed. Reg. at 41,047 — is inadequate and unexplained. It also overlooks the importance of complying with the statutory requirements and including data from the entire marketplace of laboratories.

55. The Secretary was well aware that his policy would effectively exclude hospital laboratories from reporting. Yet he asserted that "the statute supports the effective exclusion of hospital laboratories by virtue of the majority of Medicare revenues criterion in section 1834A(a)(2) of the Act." 81 Fed. Reg. at 41,045. The Secretary also cited the majority of

Medicare revenues criterion as the reason why it would be inappropriate to define "applicable laboratory" by CLIA certification number, as many commenters had proposed. *Id.*

56. The Secretary attempted to ameliorate concerns over his drastic narrowing of the statutory reporting requirements by re-defining "applicable laboratory" by reference to NPI rather than TIN. But the Secretary's final rule still does not capture the market as a whole, as Congress unambiguously directed and intended. To satisfy the Secretary's new requirement, reporting hospital laboratories would need to have secured two NPIs: one related to the hospital as a whole, under which it bills for inpatient and outpatient services, and another specifically for hospital outreach laboratory services for non-hospital patients. Without a separate laboratory NPI, the hospital laboratory would be exempt from reporting information that Congress required.

57. It is unreasonable to expect a hospital to have more than one NPI or to obtain a separate NPI for its laboratory. As ACLA explained in its comments to the proposed rule, that is not how hospital laboratories conduct their business, and it would be administratively inconvenient and burdensome for them to obtain a separate NPI. Khani Decl. Ex. 14 at 5. Instead of addressing that concern, the Secretary suggested that hospital outreach laboratories *could* obtain a unique NPI and, therefore, *could* meet his definition of applicable laboratory. 81 Fed. Reg. at 41,046.

58. That is no response at all. Hospital laboratories are not required to obtain a separate NPI distinct from the hospital NPI. The Secretary's response, therefore, leaves the choice of whether to report private payor data to the discretion of each individual hospital laboratory, contrary to Congress's directive that all "applicable laboratories" must report data. It also effectively removes Congress's threat of civil monetary penalties for those entities that fail to report. Those who fail to obtain a new and unique NPI would have no reporting requirements,

if they do not otherwise meet the Medicare threshold amounts. In fact, CMS forbade such hospitals from voluntarily submitting their data.

59. Even for those hospitals who choose to obtain a unique NPI for laboratory services, it is too late. The final rule, issued June 23, 2016, required data collection based on a January 1, 2016 through June 30, 2016 timeframe, to be reported in 2017. 81 Fed. Reg. at 41,066. In other words, only those hospitals that acted preemptively to drastically change their Medicare billing arrangement based on a provisional proposed rule would be among those who could conceivably qualify as an "applicable laboratory" under the Secretary's definition.

60. Using 2015 data, the government predicted with concern that the final rule would require reporting by only 12,547 laboratories out of a total of 261,524 laboratories (based on the number of unique NPIs which billed the Medicare program for laboratory services in 2015). In other words, the government estimated that only 5 percent of all laboratories would be required to report. *See* Office of Inspector General, Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data, OEI-09-16-0004 (Sept. 2016) at 3, 7, *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf ("OIG 2015 Data Report").

61. The actual data reported were far worse: The Secretary received private payor data from only 1,942 NPI-level entities, which included 658 independent laboratories, 1,106 physician office laboratories, 21 hospital laboratories, and 157 "other" entities. *See* Summary of Data Reporting for Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System at 3, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf ("CMS Reporting Summary").

62. Independent laboratories received approximately 55 percent of Medicare Clinical Laboratory Fee Schedule payments in 2016, and yet make up over 90 percent of the reported laboratory test volume collected by the Secretary. *Compare* OIG 2016 Data Report at 2 *with* CMS Reporting Summary at 3. As noted above, however, these laboratory types typically receive the lowest private payor rates. Shorten Decl. ¶ 12. A hidden tab labeled "Hidden Data" in the Secretary's 2018 payment rates file confirms that the two largest independent laboratories generally have lower private payor rates than other reporting entities and that including their data resulted in lower calculated Clinical Laboratory Fee Schedule payment rates. *See* CY 2018 Final Private Payor Rate-Based CLFS Payment Rates, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

63. Physician offices account for 18 percent of 2016 Clinical Laboratory Fee Schedule payments, but make up only 7.5 percent of the reported test volume. *Compare* OIG 2016 Data Report at 2 and CMS Reporting Summary at 3.

64. Of greatest concern, hospital laboratories received 26 percent of the Clinical Laboratory Fee Schedule payments in 2016, but the 21 hospital laboratories that reported data make up just 1 percent of the reported laboratory test volume. *Id.* This is the case despite the fact that the OIG concluded that, based on their NPI revenue, approximately 7,000 hospital laboratories received payments under the Clinical Laboratory Fee Schedule in 2015. *See* OIG 2015 Data Report at 8.

65. The OIG predicted this gross under-reporting of market data by hospital laboratories. In its report, the OIG stated that although nearly 7,000 hospital laboratories report some Clinical Laboratory Fee Schedule revenue, none would be required to report 2016 revenue because hospital laboratories typically do not have a separate NPI from the hospital. *Id.* Of the

very few that might, the OIG considered them to be independent laboratories. *Id.*; *see also id.* at 14 n. 25 ("Only a hospital outreach lab that obtains a unique NPI — separate from the hospital's NPI — could potentially qualify as an applicable lab. However, such labs would appear in CMS claims data — and therefore, in our analysis—as independent labs"). Accordingly, with only 21 hospital laboratories reporting, regardless of how hospital outreach laboratories are categorized by the OIG, far fewer than 1 percent of total hospital laboratories nationwide receiving reimbursement under the Clinical Laboratory Fee Schedule reported data to the Secretary. Not only does this data fail to capture the volume of hospital outreach private payor laboratory tests, the small sample size cannot adequately represent the full spectrum of rates that hospital laboratories receive. *See* Kolozsvary Decl. ¶ 24.

66. The information reported by a small subset of laboratories and collected by the Secretary is not representative of the market as a whole. The sample of laboratories that reported data is extremely small, and it excludes important market segments. As a result, it is not possible to properly calculate the weighted mean of private payor market rates for each diagnostic test.

67. Although the Secretary suggested in his final rule that collecting the additional data required by Congress would not have made any difference, the Secretary's explanation for that conclusion was inadequate, unreasonable, and irrational. The Secretary did not provide any reasoned explanation as to why this conclusion excused his failure to comply with Congress's directive to collect market data from all "applicable laboratories."

68. Having failed to collect the information that Congress required, the Secretary was in no position to take the next step called for under the statute and, under 42 U.S.C. § 1395m-1(b), establish payment rates. Nonetheless, the Secretary finalized new, nationwide rates, effective January 1, 2018. The proposed rates were published on the CMS website, not in the

Federal Register, on September 22, 2017, with the Secretary calling for comments to be submitted by October 23. *See* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html. The final rates were posted by the Secretary on November 17, 2017. *See id.*

69. Hospital laboratories often receive higher private payor rates than independent clinical laboratories, due to differences in competitive markets, volumes of services, and other factors. Kolozsvary Decl. ¶ 16; Shorten Decl. ¶ 14. Because the Secretary impermissibly excluded hospital laboratories and certain other laboratories from the statutory data-reporting requirements, the weighted median of private payor data is skewed and the proposed payment rates are significantly lower than previously estimated. These low payment rates are the consequence of the Secretary's unlawful and *ultra vires* failure to collect the data required by Congress and necessary to take into account the market as a whole.

70. Because the Secretary has not collected information from a substantial segment of the laboratories participating in the market, the Secretary now estimates that laboratories will receive dramatically reduced Part B payments — a decrease of approximately $670 million in calendar year 2018. CMS Reporting Summary at 1. That stands in stark contrast to Congress's intent. The Congressional Budget Office estimated that, by moving to a new system, Medicare payments overall would be reduced by approximately $100 million dollars the first year of Section 216's implementation — a number more than six times lower than the current estimate. *See* Congressional Budget Office, Cost Estimate for the Protecting Access to Medicare Act of 2014, *available at* https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/costestimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140.pdf.

The current estimate also nearly doubles the estimate included in the Secretary's final rule. *See* 81 Fed. Reg. at 41,092 (estimating an impact in 2018 of $390 million).

C. Current and Ongoing Harm

71. ACLA and its membership have been substantially harmed, and will continue to incur substantial future harm, as a direct result of the Secretary's decision to adopt a regulatory definition of "applicable laboratory" that alters the unambiguous definition set by Congress and exempts thousands of laboratories from the statutory reporting requirements.

72. ACLA is submitting with this complaint several declarations that set forth the substantial harm caused by the Secretary's final rule, and ACLA preserves its right to request further injunctive or other relief to ensure that those harms are appropriately redressed. The substantial harm caused by the Secretary's final rule includes:

a. The disproportionate financial and practical burden imposed on certain laboratories, including ACLA members, who are required to comply with the extensive statutory reporting requirements, while their competitors are improperly exempt from the regulatory burdens that Congress imposed. Certain laboratories have been forced to expend millions of dollars to comply with the statutory mandate, while others have been unlawfully exempted by the Secretary. *See* Shorten Decl. ¶¶ 20–30.

b. The inability of certain laboratories to report private payor information to the Secretary and have that data considered in setting national payment rates, despite Congress's statutory directive.

c. The substantial financial impact on all laboratories, which the Secretary estimates will result in a decrease in Medicare Part B payments of $670 million, nearly double the final rule's estimate of $390 million and more than six times what the Congressional Budget Office estimated when PAMA was enacted. *Compare* CMS Reporting Summary at 1, 81 Fed.

Reg. at 41,092, and https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/costestimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140.pdf.

d. The considerable ongoing reduction in Medicare Part B payments for laboratory services, estimated by the Secretary in the final rule to be $1.71 billion over 5 years and $3.93 billion over 10 years, Table 14, 81 Fed. Reg. at 41,097, but likely much higher based on his recent increase in the estimates for calendar year 2018. This negative impact is significantly higher than Congress intended, with the CBO predicting that PAMA Section 216 would result in payment reductions of $1 billion over 5 years and $2 billion over 10. *See* https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/costestimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140.pdf.

e. Small community and rural hospital laboratories will be forced to significantly scale back if not completely eliminate the outreach laboratory services they provide because they will no longer be able to afford to provide those clinical diagnostic services to non-hospital patients. *See* Kolozsvary Decl. ¶ 27.

f. Laboratories that provide clinical diagnostic services to non-ambulatory patients in institutional settings, like skilled nursing facilities and nursing homes, will be forced to significantly scale back their services, and many of these laboratories will simply be forced out of business. *See* Gudaitis Decl. ¶ 23–24.

g. As laboratories close or are required to scale back services, Medicare beneficiaries and other patients will suffer by being deprived of essential laboratory services that they need. *See* Kolozsvary Decl. ¶ 27; Gudaitis Decl. ¶ 28–31; Shorten Decl. ¶ 19.

CLAIMS

COUNT 1
Ultra Vires Agency Action Not in Accordance with Law, In Excess of Statutory Authority (42 U.S.C. § 1395m-1; 5 U.S.C. §§ 706(2)(A), 706(2)(C))

73. Paragraphs 1–72 are incorporated herein in their entirety.

74. The APA permits judicial review of agency actions, findings, and conclusions that are "not in accordance with law" or are "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. §§ 706(2)(A), 706(2)(C).

75. When "Congress has directly spoken to the precise question at issue," this Court must give effect to Congress's unambiguously stated intent. *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). It is a "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regulatory Gp. v. EPA*, 134 S. Ct. 2427, 2446 (2014).

76. Congress has defined "applicable laboratory" to mean "a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section [1834A], section 1833(h), or section 1848." 42 U.S.C. § 1395m-1(a)(2). This text is unambiguous: it requires data reporting from *all* laboratories that earn a majority of Medicare revenues under the Clinical Laboratory Fee Schedule or Physician Fee Schedule, unless exempted by the Secretary for low volume or low revenue. The term "laboratory" is unambiguous, and the phrase "its revenues" in 42 U.S.C. § 1395m-1(a)(2) refers directly to the revenues of the laboratory itself, not to a broader hospital entity, as CMS has impermissibly and unreasonably interpreted the term.

77. The Secretary's definition set forth at 42 C.F.R. § 414.502, which requires an "applicable laboratory" to also have its own NPI by which it bills Medicare Part B, conflicts with

the statutory definition Congress enacted. By adopting his own definition in conflict with the statute, the Secretary has violated an unambiguous statutory directive and specific command of the statute.

78. Congress granted the Secretary *limited* authority "to establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory . . . , as the Secretary determines appropriate." 42 U.S.C. § 1395m-1(a)(2). Under the interpretive canon *expressio unius est exclusion alterius*, by authorizing the Secretary to exempt certain laboratories from the statutory reporting requirements in defined circumstances, Congress denied the Secretary authority to exempt laboratories from those requirements in other circumstances. The Secretary therefore lacks the statutory authority to define "applicable laboratory" to exclude virtually all hospital laboratories.

79. The Secretary's final rule violates an unambiguous statutory directive under PAMA. The Secretary's action is *ultra vires* because it improperly expanded the scope of his statutory authority and rewrote the statutory requirements. Accordingly, the final rule must be set aside.

COUNT 2
Unreasonable Construction of Statute
(42 U.S.C. § 1395m-1)

80. Paragraphs 1–72 are incorporated herein in their entirety.

81. The Secretary is obligated to adopt a permissible construction of the statutory requirements. *Chevron*, 467 U.S. at 843. The Court may defer to an agency's interpretation only if it falls within "the bounds of reasonableness." *Goldstein v. SEC*, 451 F.3d 873, 881 (D.C. Cir. 2006).

82. The Secretary's definition of "applicable laboratories" categorically excludes one of the largest groups of providers of laboratory services from the reporting requirements: hospital laboratories.

83. That exclusion is unreasonable on its face. It also unreasonably conflicts with Congress's stated purpose — *i.e.*, that all laboratories receiving the majority of their Medicare revenue under the Clinical Laboratory Fee Schedule or Physician Fee Schedule would report data, except those meeting a low-volume or low-expenditure threshold.

84. The Secretary has failed to resolve this inconsistency. Instead, the Secretary has proposed to include hospital outreach laboratories that take the step of obtaining a separate NPI. That is unreasonable because in practice it does nothing to ensure the reporting of data that Congress intended. 81 Fed. Reg. at 41,045.

85. The Secretary himself acknowledged that "it was important that we define laboratory broadly enough to encompass every laboratory type that is subject to the CLFS," 81 Fed. Reg. at 41,042, and that it is an "advantage" to have "broader representation of the national laboratory market on which to base CLFS payment amounts." *Id.* at 41,046.

86. Nonetheless, the Secretary's final rule unreasonably excludes nearly all hospital laboratories, nearly all physician office laboratories, and more than half of independent laboratories from reporting private payor data. 81 Fed. Reg. at 41,045, 41,051.

87. The Secretary has not provided any reasoned justification for treating hospital laboratories different from other laboratories. Nor does his final rule respond reasonably and meaningfully to comments submitted by ACLA and others.

88. Because any "unsupported agency action normally warrants vacatur," *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir.

2005), and because the Secretary's final rule is manifestly contrary to PAMA's requirements, it must be set aside.

COUNT 3
Violation of the Administrative Procedure Act
Arbitrary and Capricious Action
(5 U.S.C. § 706(2)(A))

89. Paragraphs 1–72 are incorporated herein in their entirety.

90. The APA permits judicial review of agency actions, findings and conclusions that are "arbitrary, capricious" or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

91. Agency action is arbitrary and capricious and an abuse of discretion when the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983). The agency must provide a "rational connection between the facts found and the choice made" so as to afford a reviewing court the opportunity to evaluate the agency's decision-making process. *Id.*; *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (noting "the requirement that an agency provide reasoned explanation for its action").

92. The Secretary has arbitrarily and capriciously exempted large numbers of laboratories from the reporting requirements that Congress unambiguously imposed. The statutory text could not be clearer: it provides a definition of "applicable laboratory." 42 U.S.C. § 1395m-1(a)(2). Instead of applying that definition, the Secretary has adopted a different definition at 42 C.F.R. § 414.502, which requires an "applicable laboratory" to also have a

separate NPI under which it bills Medicare Part B. He has yet to, and cannot, provide a rational explanation for this illogical departure.

93. There is no rational connection between the Secretary's rule, which arbitrarily narrows the applicable market and ignores the unambiguous legislative directive that any "applicable laboratory" — provided it meets minimum revenue thresholds — report its data to the Secretary. 42 U.S.C. § 1395m-1(a)(2).

94. The Secretary's reasoning and explanation contradicts his final action. He acknowledged that "it was important" to "define laboratory broadly enough to encompass every laboratory type that is subject to the Clinical Laboratory Fee Schedule," 81 Fed. Reg. at 41,042, and that it is an "advantage" to have "broader representation of the national laboratory market on which to base [Clinical Laboratory Fee Schedule or Physician Fee Schedule] payment amounts." *Id.* at 41,046. Nonetheless, the Secretary's final rule excludes nearly all hospital laboratories, nearly all physician office laboratories, and more than half of independent laboratories from reporting private payor data. *Id.* at 41,045, 41,051.

95. The Secretary's notice and comment procedure was equally flawed, as he never gave serious consideration to any of the numerous objections he received to his total disregard of a statutory directive. When commenters, including ACLA, objected to the rule's attempt to exclude hospital laboratories from the statutory requirements, the Secretary did not meaningfully or adequately respond. Instead, the Secretary side-stepped that objection with circular reasoning. *Id*. at 41,045 (arguing that hospitals typically receive the majority of their revenues via the IPPS or OPPS and that hospital outreach laboratories should be accounted for in the CLFS rates). The Secretary also failed to seriously consider the input of entities, such as ACLA, with vested

interests in fair and reasonable reimbursement for laboratory services furnished to Medicare beneficiaries.

96. Moreover, the Secretary's decision to exempt large volumes of laboratories from the reporting requirements that Congress imposed implicates a "fundamental norm of administrative procedure" — the requirement that "an agency treat like cases alike." *Westar Energy, Inc. v. FERC*, 472 F.3d 1239, 1241 (D.C. Cir. 2007) (noting that if an agency makes an exception in one case, then it must either make an exception in a similar case or point to a relevant distinction between the two cases). The Secretary has offered no reasoned or reasonable explanation for why hospital laboratories should be treated differently from other laboratories, and why their private payor data should be excluded from the calculation of national payment rates if they otherwise meet the statutory requirement for revenue.

97. Because the Secretary's Final Rule is not the product of reasoned decision-making and provides no reasonable basis for the regulatory definition of "applicable laboratory," the Final Rule is arbitrary and capricious and must be vacated. *See* 5 U.S.C. § 706(2).

COUNT 4
Violation of the Administrative Procedure Act
Injunctive and Declaratory Relief
(5 U.S.C. § 706)

98. Paragraphs 1–72 are incorporated herein in their entirety.

99. The APA requires a court to "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious . . . or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

100. The APA also allows a reviewing court to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of review proceedings." *Id.* at § 705.

101. For the reasons discussed above, the Secretary's decision to adopt a regulatory definition of "applicable laboratory" that differs from that required under PAMA Section 216(a) is arbitrary, capricious, and contrary to law.

102. This Court therefore should declare that the Secretary is enjoined from enforcing the current regulatory definition of "applicable laboratory" and required to maintain current laboratory payment rates while this litigation is pending.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that this Court enter judgment in its favor:

A. Vacating any agency action found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and remand any matters herein to the Secretary for further proceedings in accord with any legal instructions the Court may deem proper and just.

B. Requiring the Secretary to change his regulations to comply with the statutory requirements, including faithfully implementing the statutory definition of "applicable laboratory."

C. Entering an injunction that (1) directs the Secretary to withdraw or suspend his final rule until such time as it can be brought into compliance with the statute, and (2) directs the Secretary to withhold applying the new Clinical Laboratory Fee Schedule until such time as the Secretary has made appropriate revisions to his final rule.

D. Ordering such other and further relief as the Court deems just and proper, including the award of costs and disbursements of this action and reasonable attorneys' fees.

Respectfully submitted,

Dated: December 11, 2017

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