Complaint Attachment A
Gudaitis Declaration

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

DECLARATION OF PETER GUDAITIS

I, Peter Gudaitis, declare the following to be true and correct to the best of my knowledge:

1. I am a resident of Monmouth County, New Jersey. I am over the age of eighteen, and I am competent to provide this Declaration.

2. I am President at Aculabs, Inc. ("Aculabs"), where I have been employed for the past 23 years. Aculabs is a member of the American Clinical Laboratory Association, and I serve on the Association's Board of Directors.

3. Aculabs was started by my father in 1972 when I was only one year old. I grew up in the lab, and the company remains a family-owned and family-operated business.

4. Because of my life-long experience with the company, I understand Aculabs' business model, the payors who reimburse Aculabs for our clinical diagnostic services, and most

significantly the beneficiaries we serve. I have worked in this industry for virtually my entire professional life, and I am very familiar with the business model of laboratories, like Aculabs, that provide clinical diagnostic services to patients in skilled nursing facilities, nursing homes, and other long-term care facilities (including long term care hospitals and assisted living facilities). I also have a deep appreciation for how changes to the Medicare system will have an impact on Aculabs' business, and the businesses of other similar labs, and how those changes will affect our ability to stay in business and provide high-quality services to Medicare beneficiaries and other patients.

5. Aculabs grew under the direction of my mother and father. They started Aculabs as a small laboratory in the basement of a local hospital that initially served only a few area physician offices. They grew the business to a much larger laboratory focused on providing services to several hundred nursing home and skilled nursing facilities across multiple states.

6. Aculabs began servicing the nursing home and skilled nursing industry in the mid-1980s. It grew in that sector because other laboratories left the market due to the high costs of providing laboratory services to older, non-ambulatory patients with high needs for chronic disease management. At the same time, Aculabs largely stopped providing services to physician offices so it could concentrate on providing laboratory services to nursing homes, skilled nursing facilities, and other long-term care facilities.

7. Aculabs' primary business today is providing laboratory services to over 320 skilled nursing facilities and assisted living facilities in New Jersey, Pennsylvania, Maryland, and Delaware. Aculabs provides services to approximately 750,000 patients every year. In its geriatric patient base alone, Aculabs performs over 10 million tests annually.

8. The large independent laboratories typically do not provide the services that nursing homes, skilled nursing facilities, and other long-term care facilities require. Their business model is focused on providing services to ambulatory patient populations that require laboratory services associated with scheduled physician visits. The laboratory testing for this population typically does not require direct, immediate physician intervention. In addition, the larger independent laboratories target more densely populated urban and suburban areas, where they can leverage higher test volumes and draw specimens at patient service centers, eliminating the need for phlebotomists to travel from patient to laboratory.

9. Aculabs' business model is very different. It serves a higher acuity, non-ambulatory patient population that has unique clinical laboratory testing needs. The patients we serve are also dispersed throughout several locations at nursing homes, skilled nursing facilities, and other long-term care facilities. As a result, Aculabs cannot perform the same volume of tests per day as large independent laboratories. Aculabs' workday typically begins very early, with phlebotomists traveling to the sites to collect the specimens for testing. The logistics involved in going from facility to facility and room to room only allows Aculabs' phlebotomists to collect specimens from six patients per hour. By comparison, it is my understanding that a large independent laboratory operating in urban areas can service 17 to 20 patients per hour.

10. Patients living in skilled nursing facilities and assisted living facilities are typically elderly and fragile, with multiple complex and chronic conditions. They are typically insured by Medicare and/or Medicaid and, due to their multiple complex and chronic conditions, they often require laboratory testing to be done on a regular basis. Drawing blood from these patients takes more time than drawing blood from younger, healthier people. Physiologically, it is more difficult to draw blood from a sick and elderly patient because they have thinner and

looser skin, lower blood pressure, and decreased vein elasticity. Elderly patients are more likely to have arthritis or other diseases or injuries that limit their range of motion and make it more difficult for a phlebotomist to access a vein to draw blood. The process of drawing blood can also be more difficult because of hearing loss or dementia.

11. Patients living in skilled nursing facilities, nursing homes, and assisted living facilities are often unable to drive or travel by other means to a hospital or physician office for care. As a result, they rely almost exclusively on laboratory services provided at the facility. But skilled nursing facilities, nursing homes, and assisted living facilities do not typically have their own full-service laboratories. Although they may have the ability to perform limited simple, non-complex testing such as finger stick glucose monitoring, long-term care facilities do not typically have the ability to provide the full range of testing required by their patients because it is cost prohibitive. Accordingly, third parties, such as Aculabs, must travel to the patients, draw the blood, bring the specimens back to the laboratory, and report results to the treating physician. This is a labor-intensive service, but it is essential to making appropriate clinical decisions.

12. Large independent laboratories can leverage the fact that they service ambulatory patients in densely populated areas by collecting samples throughout the day, and then performing the tests overnight so physician offices can receive the test results by the next day. This overnight turnaround generally meets the testing needs of that population of patients; the number of tests that large independent laboratories must perform on a rapid-turnaround basis is relatively small compared to the total volume of tests they perform.

13. By comparison, there are a number of factors that make it more costly to provide diagnostic testing services to patients who live in skilled nursing facilities, nursing homes, and

other long-term care facilities. These patients typically suffer from complex and chronic health care problems of the type that are compounded by being frail and elderly. These conditions typically require more frequent diagnostic monitoring with test results that must be reported to the patients' physicians within hours (instead of overnight) so the physician can use those results in managing the patient's care.

14. For these reasons, Aculabs and other similar laboratories send phlebotomists to skilled nursing facilities, nursing homes, and assisted living facilities to collect samples directly from patient bedsides first thing in the morning. These samples are usually collected between 5 and 6 a.m., because the physicians request the results of these tests by 12:00 p.m. in order to use them in the continuous management of their patients' chronic conditions. In addition, patients in skilled nursing facilities and nursing homes have a higher number of tests that are required to be performed "STAT" than patients served by independent laboratories. Tests are performed "STAT" when a treating physician calls Aculabs (or some other similar laboratory) to the facility for urgent testing on a single patient to manage a medical emergency. When "STAT" or emergency calls come into Aculabs, an order is placed and given directly to a "mobile" phlebotomist. That phlebotomist's sole task is rushing to the client's location, drawing blood, and then transferring the blood to the laboratory for testing, with no additional stops along the way. With STAT testing, the total lapse of time from when Aculabs receives the call to when results are provided to the treating physician is typically between 2 and 3 hours.

15. Prompt results are also very important for elderly patients in skilled nursing facilities, nursing homes, and other long-term care facilities who suffer from medical conditions that are more likely to require immediate medical care. By way of example, approximately 13 percent of the bloodwork that Aculabs performs yields "critical" or "alert" values, meaning that

the results of our tests are outside the normal, safe range and must be immediately communicated to the treating physician so that he or she can take swift medical action. Based on discussions I have had with contacts at independent laboratories, it is my understanding that independent laboratories typically have tests in the "critical" range less than one percent of the time.

16. Even though Aculabs and similar laboratories that service skilled nursing facilities and nursing homes face a higher cost to provide laboratory services to their patients, the vast majority of tests that are performed by Aculabs yield some of the lower reimbursement rates by Medicare. Approximately 75 percent of the testing done by Aculabs involves four basic tests: (1) complete blood count (CPT code 80025; used to detect such conditions as anemia, leukemia or infection), (2) prothrombin time (CPT Code 85610; used to check blood-clotting ability), (3) basic metabolic panel (CPT code 80048; used to check kidney function, electrolyte balance, and blood glucose level), and (4) comprehensive metabolic panel (CPT code 80053; testing the same as 80048, plus liver function and protein and albumin levels). These are tests with some of the lowest Medicare reimbursement rates. Aculabs' patient population does not require many of the costlier tests used for diagnosis, including molecular testing and advanced testing.

17. Aculabs has two testing facilities: one in Cherry Hill, New Jersey, and one in East Brunswick, New Jersey. Because of the travel and time demands of providing services to patients at skilled nursing facilities, nursing homes, and assisted living facilities, the patients that Aculabs can serve are limited to those who are geographically close to the location of its two laboratories. Phlebotomists who draw blood in the morning can travel only as far and to so many facilities if they are to return specimens to the laboratory in order to meet the required quick turnaround time demanded by physicians. Phlebotomists are particularly limited by geography when "STAT" testing is required.

18. If a laboratory in a different geographic area adjacent to Aculabs' service area were to be forced for business reasons to exit the laboratory business, laboratories like Aculabs would not be able to absorb the testing needs of those customers without physically expanding their laboratories into those geographic areas. Any laboratory that considered entering the market would still have to face the factors that increase the costs of providing laboratory testing services to this population, such as limitations on phlebotomist travel and the need for rapid testing turnaround time.

19. Approximately 95 percent of Aculabs' revenue is tied to the Medicare program. For patients whose laboratory services are being covered under Medicare Part B, Aculabs bills Medicare directly and is paid pursuant to the Clinical Laboratory Fee Schedule. For beneficiaries who have incurred a Part A stay at a skilled nursing facility, the facility bills Medicare directly and receives a consolidated or bundled amount for all services provided during the stay, including any laboratory services provided to the beneficiary. In turn, Aculabs bills and is paid a negotiated rate by the facility, typically expressed as a percentage of the Medicare Clinical Laboratory Fee Schedule. Aculabs' Medicare business is nearly evenly split between Part A and Part B patients. Aculabs' ability to stay in business is therefore directly and significantly tied to the reimbursement it receives from Medicare.

20. I am deeply concerned by the failure of the Secretary of Health and Human Services to faithfully implement the reporting requirements that Congress imposed in Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"). Aculabs supported that legislation because it was designed to provide the Secretary with information that would accurately represent the commercial rates paid by private payors to all sectors of the diverse clinical laboratory industry. Instead, the Secretary has failed to collect data from a large number

of market participants — including, most critically, hospital laboratories — and instead has primarily collected data from large, independent laboratories that do not reflect all sectors of the clinical laboratory market.

21. Because large sectors of the clinical laboratory market have not reported private payor data to the Secretary, as Congress required, the reimbursement rates on the Clinical Laboratory Fee Schedule are not representative of the market.

22. If the Secretary's failure to implement Congress's directives is not corrected, the impact on Aculabs' business will be severe. Starting in 2018, Aculabs will not receive Medicare-derived reimbursement sufficient to cover its costs. Instead, the Medicare payment for the four CPT codes for which Aculabs does the bulk of its testing (80025, 85610, 80048, and 80053), already on the low end of the fee schedule spectrum, will be reduced by approximately 30 percent over the next three years.

23. Excluding important sectors of the clinical diagnostic laboratory market from PAMA's reporting requirement means Armageddon for laboratories serving elderly patients in skilled nursing facilities, nursing homes, and other long-term care facilities. In the very near future, Aculabs will face critical business decisions, including being forced to drastically decrease the level of services it is able to provide to a critically sick population. If the Secretary's failure to require data reporting from all applicable laboratories is not corrected, it will only be a matter of one or two years before the company started by my father and built by my family for the last 45 years will be forced out of business.

24. Aculabs will not be alone. For example, I am already aware of one laboratory serving nursing homes and other long-term care facilities that is closing its business before

January 1, 2018. The same forces that are forcing this laboratory to close its business will cause many more nursing home laboratories to follow.

25. It is my understanding that fewer than 100 laboratories provide services to the majority of skilled nursing facilities and assisted living facilities nationwide, most of which, like Aculabs, are heavily dependent on Medicare beneficiaries for their customer base. Four of those laboratories (including Aculabs) provide 30 to 40 percent of all services. Each of the four is concentrated in certain geographic areas with little overlap. Because services to long-term care facilities are directly tethered to the location of each laboratory's testing facilities and its ability to get specimens there within hours, these laboratories are unlikely to step into the shoes of another, should one exit the marketplace. Moreover, if one of these laboratories were to exit the marketplace, the likely reason is that the marketplace was no longer profitable for Medicare patients, making it unlikely that others would attempt to enter in its stead.

26. Because of the unique medical needs of patients in long-term care facilities and the accompanying costs and challenges of providing clinical laboratory services to them, laboratories that operate in other sectors of the market, like independent laboratories or hospital laboratories, are unlikely to step in to provide services. If they did enter the long-term care market, other laboratories would provide significantly reduced services at the ultimate expense of patient health. For example, a large independent laboratory, with limited direct specimen collection ability, specified travel routes, and less of an ability to provide quick turnaround test results, would not be able to provide the services demanded by long-term care patients without changing its business model.

27. Moreover, it is unlikely that the skilled nursing facility laboratories themselves, which typically provide only limited, simple, non-complex clinical laboratory testing, will be

able to dramatically increase the services offered. To do so would require additional accreditation, staffing and equipment, which, given the small, fixed patient population at the facilities, is unlikely to be financially reasonable. This is the reason why these institutions typically contract with laboratories like Aculabs.

28. If laboratories serving skilled nursing facilities, nursing homes, and other long-term care facilities do not leave the marketplace (or if another type of laboratory were to enter the market), they will be forced to reduce the services they provide which, in turn, poses a very real and substantial threat to beneficiary health and safety For example, laboratories like Aculabs will not be able to send phlebotomists to the facility for direct collection as frequently and, as a result, patients will have to wait longer for test results.

29. There is a direct correlation between delayed laboratory results and poor health outcomes for people who rely on regular diagnostic testing for maintaining their chronic conditions. The sick and elderly patient population is unlikely to be able to be able to tolerate a slower service model.

30. In addition to increasing the risks of adverse health outcomes to these patients, reducing clinical diagnostic services to will ironically lead to more costly care. Many patients who require "STAT" testing will not be able to wait for a phlebotomist to arrive, and the facility will have no other option but to request ambulance transportation for that patient to the hospital emergency room solely for the purpose of swift diagnostic testing that otherwise could have been provided by a phlebotomist on a "STAT" run. Not only does this increase the cost of providing clinical laboratory services to those patients, it also increases the risks of collateral harm that could result from transporting frail and elderly patients to the emergency room (including exposing them to infection).

31. These problems will hit beneficiaries and patients living in rural areas the hardest, and they are at a heightened risk for adverse health outcomes. It is one thing to expect a phlebotomist to increase his or her collections in an urban or suburban area, where long-term care facilities are more densely located, but it is virtually impossible for phlebotomists who operate for laboratories in rural areas to do so. Phlebotomists working in rural areas can only cover so much ground each day. And reliance upon ambulance transportation to a hospital laboratory is not a viable option for these beneficiaries. Many rural communities are served by a single hospital, which may be the only hospital for many miles around. A rural patient needing "STAT" testing would still be required to wait a dangerously long amount of time to get access to basic, necessary clinical diagnostic laboratory testing.

32. Congress did not intend these results. Aculabs would not have supported legislative reforms if it had known that instead of collecting market data from all applicable laboratories, the Secretary instead intended to remove hospital laboratories from the statutory reporting obligations and collect data that was neither accurate nor representative of the market as a whole.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Peter Gudaitis
President
Aculabs, Inc.

12/8/2017
Date