Complaint Attachment C
Shorten 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 DERMOT SHORTEN

I, Dermot Shorten, declare the following to be true and correct to the best of my knowledge:

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

2. I am Senior Vice President, Strategy, M&A and Ventures of Quest Diagnostics, where I have been employed for approximately 9 years. I have also served in the role of Vice President, Strategy and Ventures; Vice President, Office of the Chairman; and Vice President, Shared Service Operations at Quest Diagnostics. As Vice President, Office of the Chairman, I ran Quest Diagnostics' health plan team, where I gained experience in Quest Diagnostics' laboratory pricing and pricing in the market as a whole through service contract negotiations with health plans and hospitals and acquisitions of other laboratories.

3. Before joining Quest Diagnostics, I served as Vice President, Operations Practice at Booz & Company, where I was employed for approximately 18 years. In that role, I served for more than 10 years as a strategic adviser to Quest Diagnostics.

4. I have a master's degree in natural sciences from Cambridge University, a diploma in computer science from Cambridge University, a master's degree in operations research from Lancaster University, and a master's degree in private and public management from Yale University.

5. My current job responsibilities at Quest Diagnostics include preparing a yearly laboratory services market model, which includes multiple market segments such as Medicare, Medicaid, and commercial payors. This modeling allows me to analyze where and why the laboratory market is growing or shrinking by payor type. This data is then consolidated for decision-support purposes.

6. Because of my decades-long experience with Quest Diagnostics, I have a keen understanding of its business practices and how laboratory services are billed to and paid by different payors. I also have an understanding of market dynamics and pricing in other sectors of the clinical laboratory sectors, including hospitals and smaller laboratories.

7. Quest Diagnostics is one of the largest independent laboratories in the United States, serving one in three adult Americans. As a national provider of laboratory services for Medicare beneficiaries, Quest Diagnostics has a direct stake in ensuring that the Secretary properly implements the statutory reporting requirements that Congress imposed in the Protecting Access to Medicare Act of 2014 ("PAMA").

8. Section 216 of PAMA requires the Secretary to collect data on prices paid by private payers from virtually all clinical laboratories that receive a majority of their Medicare

revenue from the Clinical Laboratory Fee Schedule and/or Physician Fee Schedule. Those laboratories that are required to report data under the statute are known as "applicable laboratories."

9. Consistent with the statutory requirements, Quest Diagnostics reported significant volumes of its private payor data to the Secretary. It is my understanding that other large, independent laboratories, including Laboratory Corporation of America ("LabCorp"), also reported private payor data to the Secretary.

10. The Secretary did not, however, collect private payor data from all applicable laboratories, as Congress intended. Instead, the Secretary excluded almost all hospital laboratories from the data-reporting requirements, which make up a large portion of the laboratory market. As a result, the data collected by the Secretary does not accurately reflect the laboratory market as a whole.

Exclusion of Hospital Laboratories Violates Congress's Directive to Collect Commercial Payor Information from All Sectors of the Clinical Laboratory Market

11. The clinical diagnostic laboratory market in the United States is not uniform. Different types of clinical laboratories serve different patient populations. Although it has a broad, nationwide reach, Quest Diagnostics typically provides a large volume of testing services to ambulatory patients in densely populated areas. In contrast, many hospitals provide clinical laboratory outreach programs in areas not typically served by large independent laboratories, such as remote and rural areas of states. Other laboratories focus on serving patients in nursing homes and skilled nursing facilities, sending phlebotomists out to draw samples from those patients.

12. Just as the market for laboratory services is not uniform, the rates paid by commercial payors are also not uniform. For example, the rates paid to Quest Diagnostics, like other large independent laboratories, are often lower than the rates paid to other laboratory entities, like hospital outreach laboratories, for the same test.

13. I have a general understanding of the reimbursement that hospitals, physician office laboratories, and other independent laboratories receive for clinical laboratory tests. This knowledge comes from Quest Diagnostics' analyses performed on information received through its acquisition of different types of laboratories, as well as my experience negotiating service agreements with health plans and hospitals.

14. Based on this information, I understand that the rates private payors typically pay hospitals are as much as 1.5 to 4 times higher than the rates they pay large independent laboratories for the same laboratory tests. This information also shows that hospital laboratories are typically paid commercial rates that are on average 160 percent higher than the rates that are paid by Medicare for the same laboratory tests. In contrast, as the data reported by laboratories under the Secretary's implementation of PAMA demonstrates, commercial payors typically pay other laboratories, such as physician office laboratories and independent laboratories, rates that are much lower than current Medicare rates.

15. By excluding almost all hospital laboratories — the entities typically with the highest commercial rates — from the requirement to report commercial payor data, the Secretary has excluded an important sector of the clinical laboratory private payor market and has failed to obtain commercial payor data from a broad spectrum of the laboratory market as Congress directed. The exclusion of hospital laboratories from the statutory reporting requirements has

resulted in new Clinical Laboratory Fee Schedule rates that do not accurately capture the broad market of laboratory prices.

16. Approximately 12 percent of Quest Diagnostics' overall laboratory revenue is paid by the Medicare Part B program, and thus the Secretary's failure to collect the market data that Congress required and the resulting reductions in the Clinical Laboratory Fee Schedule rates will negatively affect Quest Diagnostics' business.

17. The impact will likely be much larger for smaller laboratories and hospitals, which on information and belief typically have 30 to 45 percent of their volume reimbursed by Medicare. Many of these small laboratories and hospitals may already be operating on small profit margins and, given further reductions, may be forced to scale back services or move out of the laboratory business altogether. Unlike Quest Diagnostics, their business models are less equipped to take advantage of economies of scale to respond to significantly reduced reimbursement payment.

18. These reductions in laboratory services are likely to significantly impact Medicare beneficiaries and other patients that rely on these services. As explained above, many laboratories provide services in remote or rural areas of the country, or they provide a greater percentage of tests that require more immediate turnaround time. The cost of providing laboratory services in those areas and to those patient populations is higher than in more densely populated areas. Because of the high cost of service, Quest Diagnostics and other large laboratories will be limited in their ability to step in and provide the same level of services should others exit the market. As a result, many patients may be left without sufficient laboratory services.

19. By way of further explanation, because Quest Diagnostics typically serves patient populations within 70 miles of large metropolitan centers, it is unlikely to be able to significantly increase the services it provides in rural and semi-urban locations. These areas have higher service costs per unit due to lower patient volume and higher associated costs such as logistics and phlebotomist costs, among others. Quest Diagnostics is also unlikely to significantly increase its services in more specialized settings, such as nursing homes and skilled nursing facilities, which have higher service costs than other settings. For example, the patients in these settings are often not ambulatory. As a result, phlebotomists need to be onsite to draw blood for a limited number of patients. Moreover, these types of specialized settings often require rapid turnaround time for test results, which further increases the service costs. Because the cost of serving rural and specialized settings is so much higher than in those populations that Quest Diagnostics serves, Quest Diagnostics will likely be unable to serve the customers that are adversely affected by the skewed reimbursement rates in the new Clinical Laboratory Fee Schedule.

The Secretary Has Unfairly and Arbitrarily Relieved Many "Applicable Laboratories" Of Their PAMA Section 216's Reporting Obligations

20. I am familiar with the efforts that Quest Diagnostics took to comply with the data reporting requirements. My understanding is that Quest Diagnostics and other laboratories that reported private payor information were significantly disadvantaged as compared to other laboratories that, while required to report under PAMA, were excused from that obligation by the Secretary.

21. My understanding is that reporting was a difficult, resource-intensive, and burdensome task for Quest Diagnostics, costing the company almost $2 million dollars. A significant portion of this cost will need to be repeated in subsequent data reporting cycles.

22. In contrast to how the laboratory industry typically manages its claims and payment data at the *encounter* level, the Secretary required laboratories to report data at a more granular *per-test* level, providing data using the Healthcare Common Procedure Coding System ("HCPCS").

23. At Quest Diagnostics, for example, patients receiving laboratory services rarely receive only one test. Instead, a single blood-draw encounter usually covers multiple tests. Quest Diagnostics' billing system is therefore designed to manage patient accounts at the encounter level, and not at a test level. Quest Diagnostics submits electronic bills to commercial health plans at an encounter level with HCPCS-level charges. The commercial health plans usually return a remittance document with HCPCS-level payment data. When the remittance is transmitted to Quest Diagnostics electronically, Quest Diagnostics captures and retains the HCPCS-level payment data. When the health plan remits payment to Quest Diagnostics via hard copy paper remittance, Quest Diagnostics posts this payment data at the encounter level, not the individual test level. When sending a bill to the patient for remaining costs (i.e., co-insurance, deductible, denied services), Quest Diagnostics sends a single bill per encounter, not a single bill for each laboratory test.

24. A failure to report or an error in reporting could result in a penalty of $10,000 per day, per error or omission, per "reporting entity," identified by a Taxpayer Identification Number ("TIN"). Because Quest Diagnostics bills commercial payors under 32 TINs across the

company, reporting mistakes could potentially expose the company to hundreds of thousands if not millions in fines for each day.

25. Quest Diagnostics spent considerable resources to review its accumulated private payor data and devise a means by which it could disaggregate its encounter-level payment information into meaningful test-level information.

26. The Secretary provided direction to laboratories on the manner in which data was to be collected well after the relevant dates of service, meaning that laboratories could not have changed their billing and accounting systems prospectively to better manage the Secretary's requirements. Because Quest Diagnostics historically has not captured all private payor data at the HCPCS level, and because payment data is stored in various areas across its computer systems, it had to build a system from scratch to properly report data.

27. Quest Diagnostics reported information for approximately 93 million HCPCS code-level transactions. Building systems, designing processes, and collecting this information took over two years. During this time, Quest Diagnostics representatives met frequently with agency officials over a period of approximately two years to discuss its problems with reporting applicable information.

28. Approximately 93 percent of the reportable "applicable information" was remitted to Quest Diagnostics by private payors via an electronic format — a HIPAA Standard Transactions-compliant ANSI 835 file — and included HCPCS-level information. The other 7 percent of data was remitted from payors to Quest Diagnostics in paper format. Extracting test-level payment data from these manual remittances to fulfill the Secretary's reporting requirements was a very complex task.

29. Quest Diagnostics hired two outside firms to process the approximately 3.4 million encounter-level paper remittance document images for the relevant data collection period, which was the first six months of 2016. At the peak of these vendors' production, approximately 240 people worked 6 days a week for approximately 8 weeks to complete this project. Gathering the data entailed transcribing HCPCS-level data from thousands of different payors, all with their own document layout format and content. Although Quest Diagnostics does some remittance document scanning to recognize text in an automated matter, it tried to use this technology for the PAMA transcription effort, but found that this process could not be replicated, due to the lack of standards in remittance advice document format and content. As a result, the 3.4 million encounter-level paper remittance documents had to be transcribed by hand. This raw data was also entered into the data warehouse, where it was further filtered, refined, and quality-checked before it could be submitted to the Secretary.

30. The cost of this data reporting imposed an enormous burden on Quest Diagnostics that was not imposed on the other laboratories that, under the Secretary's rule, were improperly and arbitrarily exempted from reporting the information Congress required. These laboratories unfairly escaped the costs of data collection, processing, and reporting, and are not subjected to civil penalties. As a result, they received a competitive advantage that Congress never intended them to have over laboratories, like Quest Diagnostics, that were required to report private payor data.

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

Dermot Shorten

Dermot Shorten
Senior Vice President, Strategy, M&A and Ventures
Quest Diagnostics

December 8, 2017
Date