April 10, 2020

The Honorable Tammy Duckworth
United States Senate
524 Hart Senate Office Building
Washington, DC 20510

The Honorable Richard Durbin
United States Senate
711 Hart Senate Office Building
Washington, DC 20510

The Honorable Edward Markey
United States Senate
255 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Duckworth, Durbin, and Markey:

We are the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA). Our members work in regional and community independent clinical laboratories across the United States performing clinical laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care professionals.

We are writing in response to your April 8 letter to Admiral Brett Giroir and CMS Administrator Seema Verma. While we appreciate and share your goal to scale up testing capacity in the United States. in response to the novel coronavirus pandemic, we are concerned that the regulatory flexibilities that you outline could present additional risks to Americans as we lose sight of the need to ensure that the diagnostic tools we are using are producing accurate and reliable results.

We outline some of these concerns below but welcome the opportunity to meet with you or your staff to discuss these issues in more detail.

Waived Tests

The letter requests further guidance and lenience on the use of "waived" tests. "Waived" tests, although useful in certain circumstances, are inappropriate to respond to the current pandemic and have previously been misused, resulting in harm to the public. The CLIA statute allows three ways a clinical laboratory test can be "waived." These include tests which:

> "(A) have been approved by the Food and Drug Administration for home use,
>
> (B) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or

(C) the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly."

None of the COVID-19 tests currently available are appropriate for waiver under any of these three categories. The clearest of these criteria is FDA approval for home use, which has not yet happened for any COVID-19 testing kits. Criterion (C) is not applicable for COVID-19 testing as there is a very reasonable risk of harm to a patient if a COVID-19 test is performed incorrectly.

Criterion (B) is also of concern in a pandemic situation. Criterion (B) requires methodologies that are "so simple and accurate as to render the likelihood of erroneous results negligible." A false negative on a COVID-19 test will have significant consequences on our ability to control this pandemic. Infected individuals will unknowingly continue to spread the virus, resulting in more hospitalizations and deaths. A false positive test result could unnecessarily require individuals to remain in quarantine, prevent them from interacting with their loved ones or returning to the workforce, and cause undue mental stress and anxiety. Because of the significant consequences of an erroneous result, we urge the FDA not to place any COVID-19 tests into this category.

There are several examples of the FDA classifying tests as "waived" that have gone poorly. Perhaps the best-known example is FDA's approval and waiver of Theranos' first test. In retrospect, it was apparent this was a huge mistake, and hundreds of people were misled because of this decision. A similar result in COVID-19 testing could result in a spate of false positive or false negative results, which could result in patient harm and potential further spread of the disease.

Right now, we do not have an accurate picture of how currently available COVID-19 tests perform in the clinical setting. Neither the FDA, CDC, nor CMS know the actual false positive and false negative rates of any of the COVID-19 tests, including those that are classified as high complexity. An April 2, 2020, story in the *Wall Street Journal* by Christopher Weaver claims "Health experts say they now believe nearly one in three patients who are infected (with COVID-19) are nevertheless getting a negative test result."

Proficiency Testing

In your letter you ask CMS to ensure that COVID-19 testing laboratories do not face "unnecessary restrictions on CLIA license requirements," citing 42 C.F.R. Sect. 498.801.

That section of the CLIA regulations requires that every laboratory enroll in a proficiency testing program. Proficiency testing is the cornerstone of the original CLIA statute and regulations because it provides data about the accuracy and reliability of COVID-19 test systems "in the field" (as compared to manufacturers' controlled validation studies).

While we are all anxious to increase our nation's testing capacity for COVID-19, loosening restrictions on the accuracy of these tests is **not** the answer. Now, more than ever, we need to know that laboratory tests performed in CLIA certified laboratories are accurate. Requiring laboratories to participate in proficiency testing is integral to achieving that goal.

Your letter does not mention proficiency testing for COVID-19 tests. AAB runs one of several CLIA-approved proficiency testing programs. We reached out to CDC and offered to set-up a COVID-19 emergency proficiency testing program a few weeks ago and asked if CDC could help us obtain positive specimens, but we did not receive an answer. So AAB launched its own proficiency testing program for COVID-19 on April 8, 2020.

CLIA does not require proficiency testing for "waived" tests, so there will be no proficiency testing data to analyze the "in the field" performance of "waived" COVID-19 tests, should the FDA approve "waived" tests for COVID-19.

Staffing and Personnel Qualifications

It is not our experience that CLIA requirements for testing personnel have resulted in a shortage of qualified laboratory testing personnel. In fact, many laboratories are being forced to layoff or furlough CLIA-qualified testing personnel because routine (non COVID-19) testing volumes have decreased dramatically due to the pandemic-induced closure of many medical clinics, surgery centers, and other health care facilities.

Further, current CLIA regulations do not prevent qualified PhD-level scientists or post-doctoral research fellows from working in CLIA laboratories. Section 493.1489 of the current CLIA regulations states:

> **§ 493.1489 Standard; Testing personnel qualifications.**
>
> Each individual performing high complexity testing must–
>
> (a) Possess a current license issued by the state in which the laboratory is located, if such licensing is required; and
>
> (b) Meet one of the following requirements:
>
> (1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a **doctoral, master's or bachelor's degree** in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

As you can see, individuals with a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, including post-doctoral researchers, can perform high complexity testing for COVID-19, allowing a broad range of well-qualified individuals to work in laboratory settings. We are not clear what type of individual is qualified to perform high-complexity testing without meeting CLIA's existing personnel requirements in Section 493.1489.

The policy changes proposed in your letter, while well intentioned, could have the unintended outcome of putting Americans in danger. Many tests and test-systems have been fast-tracked for clinical use to increase COVID-19 testing volume. However, these emergency authorized tests are currently required to be performed in CLIA-certified laboratories. These laboratories, by definition, have the necessary quality control procedures in place, and having properly trained

and qualified testing personnel perform these tests ensures the fewest false positive and false negative results. If COVID-19 tests or test-systems are categorized as "waived," this data will never be known. Without CLIA required quality systems (quality control, quality assurance, and proficiency testing) in place, there will be no independent verification of the functionality and performance of these tests and test-systems. The public would be solely dependent on manufacturer's claims of functionality, which may or may not be accurate.

We urge you to reconsider the position of your letter and focus instead on providing clinical laboratories with what they need to combat COVID-19: a supply-chain that provides the much-needed kits to run these tests; funding to keep qualified personnel working given the decrease in routine testing; and the purchase of necessary reagents and supplies. This is what the American people need and deserve.

Sincerely yours,

Mark S. Birenbaum, Ph.D.
Executive Director

American Association of Bioanalysts *and the*
National Independent Laboratory Association