NATIONAL INDEPENDENT LABORATORY ASSOCIATION

October 19, 2020

Secretary Alex M. Azar II
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of the National Independent Laboratory Association (NILA), whose members work in regional and community independent clinical laboratories across the United States, we write regarding the Food and Drug Administration's recent decision to cease review of emergency use authorization (EUA) applications for laboratory-developed tests (LDTs) for COVID-19. NILA is concerned that this decision will result in coverage denials for COVID-19 tests and jeopardize protections afforded to laboratories under the Public Readiness and Emergency Preparedness Act (PREP Act). NILA respectfully requests that the Department of Health and Human Services issue guidance to address both of these issues, clarifying that LDTs must be covered by health insurance consistent with the Families First Coronavirus Response Act (FFCRA) and CARES Act and use available regulatory authority to designate LDTs for the identification or diagnosis of COVID-19 as qualified pandemic or epidemic products under the PREP Act.

The FFCRA as amended by the CARES Act generally requires health plans to cover, without cost sharing, in vitro diagnostic tests for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, including tests approved, cleared, or authorized by the FDA – under an EUA or otherwise. However, neither law requires that health plans provide coverage for LDTs for the detection of SARS-CoV-2 or the diagnosis of COVID-19. To date, many independent laboratories have pursued EUA of their COVID-19 LDTs to both benefit from the protection of the PREP Act and to ensure that patients have coverage, and laboratories are reimbursed for LDTs performed to respond to the COVID-19 pandemic. The FDA's recent decision, however, leaves both independent laboratories and patients without assurance that health plans will cover LDTs for the detection and diagnosis of COVID-19.

Importantly, the CARES Act Section 3201 permits the Secretary to require coverage of any "other test that the Secretary determines appropriate in guidance." To ensure that laboratories are reimbursed for their services and that patients have access to adequate COVID-19 testing, we respectfully urge the agency to issue guidance consistent with the CARES Act that requires health plans to provide coverage, without cost sharing, for all COVID-19 LDTs developed by appropriately certified CLIA laboratories. Such a designation by the agency would not increase health care cost but would, instead, maintain access to vital LDTs that are necessary for an adequate response to the current public health emergency.

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In addition, NILA respectfully requests that the agency use its regulatory authority to ensure that LDTs used to respond to the COVID-19 pandemic are protected under the PREP Act. The PREP Act encourages independent laboratories to respond to public health emergencies by limiting liability exposure for in vitro diagnostics. PREP Act protection, however, is limited to those drugs, biological products, or devices that are, among other inapplicable provisions, approved, licensed, or cleared by the FDA or authorized for emergency use. Two recent actions by the agency—declining to review LDTS for EUA and the rescission of guidance and other informal issuances concerning premarket review of LDTs – mean that LDTs can neither be approved, licensed, nor cleared by the FDA or authorized for emergency use. As a result, without agency intervention, LDTs may not be afforded protection under the PREP Act, exposing independent laboratories to legal liability not faced by test manufacturers with access to the EUA process. NILA urges the agency to use its regulatory authority—through rulemaking, agency advisory opinion, or another appropriate mechanism—to ensure that LDTs are included among the qualified pandemic or epidemic products afforded protection under the PREP Act. Failure to do so will limit patient access to testing services by disincentivizing independent laboratory innovation to respond to the current public health emergency.

While NILA recognizes that the agency must judiciously allocate scarce resources, the decision to allocate resources away from the EUA process has significant regulatory, reimbursement, and patient access implications. NILA respectfully urges the agency to account for these implications by using its authority under the CARES Act and PREP Act to require health plan coverage of LDTs and extend protection to LDTs as qualified pandemic or epidemic products. This action will maintain patient access to laboratory services, ensure adequate reimbursement for LDTs, and encourage laboratory innovation in response to the COVID-19 public health emergency.

Thank you for your consideration.

Sincerely yours,

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.
Executive Director
National Independent Laboratory Association

CC: Stephen Hahn, M.D. – Commissioner of the FDA
CC: Seema Verma – Administrator of the Center for Medicare and Medicaid Services