Congress of the United States Washington, DC 20515

July 7, 2020

The Honorable Alex M. Azar II Secretary U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

The Honorable Eugene Scalia Secretary U.S. Department of Labor 200 Constitution Avenue NW Washington, DC 20210

The Honorable Steven T. Mnuchin Secretary of the Treasury U.S. Department of the Treasury 1500 Pennsylvania Avenue NW Washington, DC 20220

Dear Secretary Azar, Secretary Scalia, and Secretary Mnuchin:

We write to express serious concerns regarding the Administration's implementation of the Families First Coronavirus Response Act (the Families First Act)¹ and the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act).² There have been troubling reports regarding some health plans refusing to provide coverage of tests for the coronavirus disease of 2019 (COVID-19).³ Your agencies' recently issued guidance regarding insurers' and group health plans' obligation to cover the costs of testing and other related services will result in increased barriers to COVID-19 testing and pose a serious threat to the testing access needed to protect the nation's public health. With COVID-19 cases skyrocketing and our testing capacity nowhere near where it needs to be, it is unacceptable that this Administration's priority seems to be giving insurance companies loopholes instead of getting people the free testing they need. We believe this guidance is contrary to statute, and urge you to take immediate action to clarify the obligations of group health plans and insurers to provide robust and comprehensive coverage of COVID-19 testing.

¹ Families First Coronavirus Response Act, Pub. L. No. 116-127 (2020).

² Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136 (2020).

³ The \$7,000 Covid Test: Why states are stepping in to shield consumers, Politico (June 8, 2020); Testing Nursing Home Workers Can Help Stop Coronavirus. But Who Should Pay?, The New York Times (June 9, 2020).

Increasing the availability of and access to COVID-19 testing is vital in stopping the spread of the virus, and in safely reopening our communities. Top public health experts, including former Food and Drug Administration (FDA) Commissioners Scott Gottlieb and Mark McClellan, have called for robust testing to combat COVID-19, writing in their recently published report that "same-day, point-of-care diagnostic testing is crucial for identifying cases, including those with asymptomatic and mild infections." On average, 600,000-650,000 tests are now conducted each day, far short of the nearly 900,000 tests that public health experts believe we need to conduct daily in order to safely reopen the country and manage COVID-19 outbreaks. Indeed, some experts project the daily testing rate needs to be even higher.

Expanding testing capacity and accessibility are critical steps to safely reopen the country in a way that protects public health and prevents new infections and deaths. Public health experts have also stressed the need to dramatically increase COVID-19 contact tracing resources. In April, Congress provided an initial \$25 billion to expand state and local testing capacity and to increase contact tracing capabilities.

Health insurance companies should not be exempted from covering the needed testing to help protect Americans and restart the economy. The Families First Act requires individual health insurance coverage and group health plans to provide coverage of diagnostic tests for the detection of COVID-19 without any cost-sharing requirements, including deductibles, copayments, and coinsurance. The law also prohibits prior authorization or other medical management requirements for COVID-19 testing. Additionally, the Families First Act requires individual and group market health plans to provide coverage for health provider office visits, including urgent care visits and emergency room visits that result in an order of or administration of an in vitro diagnostic test at zero cost-sharing. The CARES Act requires individual and group market health plans to cover a broad range of items and services in order to detect COVID-19 without any cost-sharing, including serological tests used to detect antibodies against COVID-19. In sum, both laws require health plans to provide coverage of all COVID-19 tests and related services without any cost-sharing and without limitations.

⁴ American Enterprise Institute, *National coronavirus response: A road map to reopening* (Mar. 2020).

⁵ U.S. Coronavirus Testing Still Falls Short. How's Your State Doing?, National Public Radio (May 7, 2020).

⁶ National Governor's Association and the Association of State and Territorial Health Officials, *Roadmap to Recovery: A Public Health Guide for Governors* (Apr. 21, 2020).

⁷ U.S. health insurers may balk at paying for coronavirus antibody testing, Reuters (June 16, 2020) (www.reuters.com/article/us-health-coronavirus-usa-testing-focus/u-s-health-insurers-may-balk-at-paying-for-coronavirus-antibody-testing-idUSKBN23N1PD).

Congress's primary goal with both laws was to increase access to widespread testing, and to eliminate any financial barriers to individuals receiving COVID-19 tests. Not only did Congress mandate coverage of a broad range of tests and services without cost-sharing, but we also explicitly prohibited the use of prior authorization or other utilization management requirements for COVID-19 testing.⁸

On April 18, 2020, the Departments of Health and Human Services (HHS), Labor, and the Treasury issued guidance implementing both the Families First Act and the CARES Act. The guidance required individual insurance coverage and group market health plans to provide coverage for items and services related to tests for the detection of COVID-19, including serological tests used to detect antibodies against COVID-19 without any cost-sharing. The guidance also required that insurers and group health plans cover any COVID-19 items and services that are medically appropriate for an individual. On June 23, 2020, the Departments of HHS, Labor, and the Treasury issued updated guidance providing the additional clarification that COVID-19 testing for surveillance or employment purposes are not required to be covered under section 6001 of the Families First Act, and that "testing conducted to screen for general workplace health and safety (such as employee 'return to work' programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section

⁸ "A group health plan or a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b-5(g)) beginning on or after the date of the enactment of this Act: (1) In vitro diagnostic products (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 (2) Items and services furnished to an individual during health care provider office visits (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product." Section 6001 (a)(1) of Pub. L. No.116-127.

⁹ Centers for Medicare and Medicaid Services, *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42* (Apr. 11, 2020) (www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf).

6001 of the [Families First Act]."¹⁰ We find the Administration's revised guidance deeply concerning as it appears to be a change that is without basis in the plain language of the statute.

The requirement that the testing be "primarily intended for individualized diagnosis or treatment of COVID-19" was not included in the statutory language of the Families First Act and the CARES Act. This interpretation of the Families First Act is not supported by the statute, which makes clear that health plans are required to cover, without any conditions or limitations, the specified items and services related to diagnostic tests for the detection of COVID-19. 11

There have been troubling reports of insurers' refusal to follow these broad coverage requirements. A number of insurers are declining to provide coverage of COVID-19 serology testing. Some insurers are providing coverage only for people who exhibit symptoms consistent with COVID-19, and are refusing to provide coverage of tests for asymptomatic individuals, including as part of public health monitoring efforts. The *New York Times* reported on a nursing home worker whose insurer refused to cover the cost of a COVID-19 test, and on nursing homes that are declining to pay for coverage of COVID-19 tests for their employees. There have also been reports of self-funded health plans' refusing to pay for COVID-19 tests at all or requiring cost-sharing from consumers, both of which are prohibited under the law.

As communities across the country reopen and people return to in-person work, it is critical that everyone has access to COVID-19 tests without any financial barriers. Widespread testing must be in place to detect and stop the spread of COVID-19 and ensuring safety in the workplace is critical. The Administration's refusal to expand testing and failure to implement a comprehensive, coordinated, national testing strategy greatly hinders our national response to COVID-19 and poses severe consequences for communities across the country. President

¹⁰ Centers for Medicare and Medicaid Services, *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43* (June 23, 2020) (www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf).

¹¹ Pub. L. No. 116-127 (2020).

¹² Insurers limit which coronavirus tests they'll pay for, Axios (June 10, 2020).

¹³ Testing Nursing Home Workers Can Help Stop Coronavirus. But Who Should Pay?, The New York Times (June 9, 2020).

¹⁴ *Id*.

¹⁵ Congress said COVID-19 tests should be free – but who's paying?, Modern Healthcare (May 22, 2020).

Trump's statements regarding testing ¹⁶ and the Administration's failure to prioritize expanded testing is putting lives at risk.

It is critical that all Americans have access to COVID-19 testing without any financial barriers. We request that HHS, Labor, and the Treasury immediately reexamine their June 23, 2020, guidance and clarify the obligations of health plans to provide coverage of COVID-19 diagnostic and serologic tests without cost sharing in all circumstances. While there may certainly be some circumstances that are beyond the scope of the coverage mandate, and circumstances in which it may be more appropriate for the state or federal government to shoulder the financial costs of testing, the language of the Families First Act and the CARES Act should be interpreted broadly to ensure the widest possible availability of testing at no cost to patients.

We request that you respond to the following questions by July 14, 2020:

- 1. When did HHS, Labor, or the Treasury become aware of insurers' refusal to provide coverage of COVID-19 tests without cost-sharing? Please provide copies of any such complaints, as well as any documentation of action your Departments have taken in response.
- 2. Why did the Departments explicitly revise the guidance to exempt plans from providing coverage for COVID-19 testing for surveillance or employment purposes?
 - a. Did the Departments issue the revised guidance at the direction of the White House?
 - b. Please provide all documents and communications between HHS, Labor, the Treasury, and Centers for Medicare and Medicaid Services (CMS) employees, and employees of the Executive Office of the President, including the Office of Management and Budget, referring or relating to the FAQs "Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43."¹⁷
 - c. Please provide a comprehensive list of all agency personnel at HHS, Labor, the Treasury, and CMS who were involved in any way in promulgating, reviewing, or finalizing the guidance.

¹⁶ Maegan Vazquez, Trump now says he wasn't kidding when he told officials to slow down coronavirus testing, contradicting staff, CNN (June 23, 2020).

¹⁷ *See* note 10.

- 3. When will HHS, Labor, and the Treasury issue guidance to clarify that coverage of COVID-19 tests must be provided without any cost-sharing regardless of an individual's health condition?
- 4. What actions will HHS, Labor, and the Treasury take to ensure insurers, group health plans, and providers are in compliance with both the Families First Act and the CARES Act?

Thank you for your attention to this urgent matter. If you have further questions, please contact Saha Khaterzai with the House Committee on Energy and Commerce at 202-225-2927, Daniel Foster with the House Committee on Education and Labor at 202-225-3735, Melanie Egorin with the House Committee on Ways and Means at 202-215-3625, Colin Goldfinch with the Senate Committee on Health, Education, Labor, and Pensions at 202-224-7675, and Arielle Woronoff with the Senate Committee on Finance at 202-224-4515.

Sincerely,

Frank Pallone, Jr.

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Chairman

Committee on Energy and Commerce

Robert C. "Bobby" Scott

Chairman

Committee on Education and Labor

Richard E. Neal

Chairman

Committee on Ways and Means

Patty Murray

Ranking Member

Committee on Health, Education,

Labor, and Pensions

Ron Wyden

Ranking Member

Committee on Finance

Ron Wyden