CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

February 24, 2020

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "The Fiscal Year 2021 HHS Budget and Oversight of the Coronavirus

Outbreak "

On Wednesday, February 26, 2019, at 1:30 p.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled, "The Fiscal Year 2021 HHS Budget and Oversight of the Coronavirus Outbreak." The purpose of this hearing is to examine the President's fiscal year (FY) 2021 budget for the Department of Health and Human Services (HHS), and to discuss the developing outbreak of the coronavirus and HHS's response.

I. THE PRESIDENT'S BUDGET REQUEST FOR FISCAL YEAR 2021

On February 10, 2020, the Trump Administration released its FY 2021 budget proposal. In total, the proposal includes a 12 percent cut to the enacted FY 2020 HHS budget – one of the largest cuts among all the federal agencies. Below are a number of highlights of the cuts included in the budget.

A. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

i. Medicare

The budget cuts the Medicare program by \$500 billion over 10 years, including reductions in uncompensated care payments to hospitals, graduate medical education payments, payments to on-campus hospital outpatient departments and other hospital related cuts. In 2019, Medicare was responsible for the health coverage of about 60 million seniors and individuals with disabilities.

ii. Medicaid

The budget cuts \$920 billion from Medicaid over ten years. Medicaid covers over 70 million individuals, which makes it the largest source of health coverage in the country. The Trump Administration budget proposes to cut \$744 billion from Medicaid as part of the President's "health reform vision," but does not specify policies to achieve these cuts. Among the other policies included in this budget are proposals to implement more restrictive eligibility

criteria on several Medicaid populations, including many children, pregnant women, and people with disabilities.

iii. Affordable Care Act

The budget cuts \$100 billion from the Affordable Care Act (ACA) and the private insurance market over 10 years. The budget does not provide policy proposals or specific details, including the number of individuals whose health coverage will be impacted by the cuts. Currently, the ACA's policies cover more than 20 million individuals' and families' health coverage, including 10 million on the ACA Marketplaces and 12 million as a result of Medicaid expansion.

D. NATIONAL INSTITUTES OF HEALTH (NIH)

The budget cuts approximately \$3 billion from the National Institutes of Health, including a \$559 million cut from the National Cancer Institute and a \$430 million cut from the National Institute of Allergy and Infectious Diseases, both of which are responsible for life-saving medical research and treatment.

E. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The budget cuts over \$625 million from the Centers for Disease Control and Prevention. This amounts to a nine percent overall cut to the agency that is responsible for preventing and controlling costly chronic health conditions and responding to disease outbreaks and emerging public health threats.

F. FOOD AND DRUG ADMINISTRATION (FDA)

The budget proposes to remove the Food and Drug Administration's current authority over tobacco products. It also proposes to establish an entirely new, not yet well-defined agency within HHS that would regulate tobacco products. This newly created agency would be led by a Senate-confirmed director.

II. CORONAVIRUS OUTBREAK

A. Background

Coronaviruses are a large family of zoonotic viruses, some causing illness in people and others that circulate among animals.¹ Coronaviruses are known to cause illnesses ranging from common colds to more severe respiratory diseases.² On February 11, 2020 the World Health Organization announced an official name for the disease that is causing the current outbreak of

¹ World Health Organization, Health Topics, Coronavirus (www.who.int/health-topics/coronavirus) (accessed Feb. 20, 2020).

 $^{^{2}}$ Id.

coronavirus disease, COVID-19.³ COVID-19 is a new disease, caused by a novel coronavirus that has not previously been seen in humans. This disease was first identified during an investigation last December into an outbreak in Wuhan, China.⁴ Public health officials have not been able to identify the original animal source of the virus that causes COVID-19.⁵

The disease is characterized by a range of symptoms, the most common being fever, cough, and shortness of breath, and the severity of cases have varied from mild symptoms to severe illness and death.⁶

The first cases of COVID-19 were detected in Wuhan City, Hubei Province, China in December 2019.⁷ As of February 20, 2020, 30 countries have confirmed cases.⁸ Globally, the virus is believed to have infected over 75,000 people and resulted in over 2,000 fatalities.⁹ In the United States, the risk to the general public remains low. As of February 20, there have been 34 confirmed cases in the United States, including 11 travel related cases, two cases of transmission to people who had not recently been to China, and 21 cases from persons repatriated to the United States from overseas.¹⁰ There are 413 cases that are still pending investigation.¹¹ The situation continues to evolve rapidly, with new cases being reported each day.

³ World Health Organization, *WHO Director-General's remarks at the media briefing on 2019-nCov on 11 February 2020* (Feb. 11, 2020) (www.who.int/dg/speeches/detail/who-director-general-s-remarks-at-the-media-briefing-on-2019-ncov-on-11-february-2020).

⁴ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-10), Frequently Asked Questions and Answers (www.cdc.gov/coronavirus/2019-ncov/faq.html) (accessed Feb. 20, 2020).

⁵ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19) Situation Summary (www.cdc.gov/coronavirus/2019-ncov/summary.html) (accessed Feb. 20, 2020).

⁶ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19) Situation Summary/About COVID-19/Symptoms (www.cdc.gov/coronavirus/2019-ncov/about/symptoms.html) (accessed Feb. 20, 2020).

⁷ World Health Organization, *Novel Coronavirus* (2019-nCoV) Situation Report 1 (Jan. 20, 2020) (www.who.int/docs/default-source/coronaviruse/situation-reports/20200121-sitrep-1-2019-ncov.pdf?sfvrsn=20a99c10_4).

⁸ Centers for Disease Control and Prevention, Locations with Confirmed COVID-19 Cases Global Map (www.cdc.gov/coronavirus/2019-ncov/locations-confirmed-cases.html#map) (accessed Feb. 21, 2020).

⁹ World Health Organization, *Novel Coronavirus (COVID-19) Situation Report* 29 (Feb. 19, 2020) (www.who.int/docs/default-source/coronaviruse/situation-reports/20200219-sitrep-30-covid-19.pdf).

¹⁰ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19) in the U.S. (www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html) (accessed Feb. 19, 2020).

¹¹ *Id*.

B. Federal Response

Despite the low number of cases in the United States currently, the federal government has taken several steps in response to this outbreak. On January 31, Secretary Azar declared a formal public health emergency in response to the rising global threat of COVID-19. 12 On February 3, CDC submitted an Emergency Use Authorization (EUA) package to the FDA in order to expedite the permitted use of the CDC diagnostic panel in the United States. 13 The EUA process enables FDA to consider and authorize the use of unapproved, but potentially life-saving medical or diagnostic products during a public health emergency. 14

Thus far, the federal government has access to \$136 million in federal funding from an HHS infectious disease Rapid Response Fund. Secretary Azar also holds the authority to transfer up to \$136 million from various HHS accounts to respond to this public health emergency. Congressional Democrats have been urging the Trump administration to request emergency supplemental appropriations to respond to the outbreak since the beginning of February. Departing from HHS and OMB's previous statements that there are already sufficient resources available to respond to COVID-19, ¹⁶ the Trump administration is reportedly preparing to request emergency funds from Congress as soon as February 24. ¹⁷

CDC now hopes to use public health labs in Chicago, New York City, Los Angeles, San Francisco and Seattle to screen samples collected by its national flu-surveillance network for

¹² Department of Health and Human Services, *Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus* (Jan. 31, 2020). (www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html).

¹³ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19), CDC Tests for COVID-19 (www.cdc.gov/coronavirus/2019-ncov/about/testing.html) (accessed Feb. 19, 2020).

¹⁴ *Id*.

¹⁵ House Committee on Appropriations, *Lowey, DeLauro Urge Administration to Request Emergency Funding for Coronavirus Response* (Feb. 4, 2020) (appropriations.house.gov/news/press-releases/lowey-delauro-urge-administration-to-request-emergency-funding-for-coronavirus) (press release).

¹⁶ Centers for Disease Control and Prevention, *Transcript for CDC Media Telebriefing: Update on COVID-19* (Feb. 14, 2020) (www.cdc.gov/media/releases/2020/t0214-covid-19-update.html.html).

¹⁷ White House to ask Congress for emergency coronavirus funding, Politico (Feb. 22, 2020) (www.politico.com/news/2020/02/22/emergency-coronavirus-funding-116761).

COVID-19.¹⁸ However, the CDC has confirmed problems with the coronavirus diagnostic testing occurring in locations outside of CDC headquarters in Atlanta.¹⁹ Additionally, some states and localities have raised concerns about the costs they are incurring, including whether they will be reimbursed.²⁰

The COVID-19 outbreak may also have long-term impacts related to consumer goods, including our drug and device supply chain. China is an important global manufacturer of pharmaceutical products and accounts for 13 percent of the world's active pharmaceutical ingredients (API).²¹ In addition to API, other products, including personal protective equipment such as surgical masks, gowns, and gloves are manufactured in China. The COVID-19 outbreak has raised concerns about disruptions in the medical product supply chain, and FDA Commissioner Stephen Hahn recently stated that he believes shortages of critical medical products are likely.²² FDA has announced that the agency is taking steps to mitigate impacts on the supply chain.

¹⁸ *Id*.

¹⁹ Centers for Disease Control and Prevention, *CDC Media Telebriefing: Update on COVID-19* (Feb. 21, 2020) (www.cdc.gov/media/releases/2020/a0221-cdc-telebriefing-covid-19.html).

²⁰ Wall Street Journal, *Amid Coronavirus*, U.S. Cities Stretch to Monitor Self-Quarantined Americans (Feb. 19, 2020).

²¹ Safeguarding the Pharmaceutical Supply Chains in a Global Economy: Hearing before the H. Comm. on Energy and Commerce, Subcomm. on Health (Oct. 30, 2019) (statement of Janet Woodcock, M.D.).

²² Food & Drug Administration, *FDA's Actions in Response to 2019 Novel Coronavirus at Home and Abroad* (Feb. 14, 2020) (www.fda.gov/news-events/press-announcements/fdas-actions-response-2019-novel-coronavirus-home-and-abroad).

III. WITNESSES

Panel I – FY 2021 HHS Budget

The Honorable Alex Azar

Secretary

U.S. Department of Health and Human Services

Panel II - Coronavirus

The Honorable Alex Azar

Secretary

U.S. Department of Health and Human Services

Anthony S. Fauci, M.D.

Director

National Institute for Allergy and Infectious Diseases National Institutes of Health

The Honorable Stephen M. Hahn, M.D.

Commissioner of Food and Drugs U.S. Food and Drug Administration

The Honorable Robert Kadlec, M.D.

Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services

Robert R. Redfield, M.D.

Director

Centers for Disease Control and Prevention