

MEMORANDUM

May 12, 2020

To: Subcommittee on Health Members and Staff

Fr: Subcommittee Chair Eshoo Staff

Re: Hearing on “Protecting Scientific Integrity in the COVID-19 Response”

On Thursday, May 14, 2020, at 10 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled, “Protecting Scientific Integrity in the COVID-19 Response.”

I. COVID-19 PANDEMIC

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 (WHO) announced an official name for the disease that is causing the 2019 novel coronavirus outbreak, first identified in Wuhan, China.³ The name of this disease is coronavirus disease 2019, abbreviated as COVID-19. COVID-19 is caused by a coronavirus called SARS-CoV-2.⁴ The exact source of this virus is unknown.⁵ On March 11, the WHO declared that the spread of COVID-19 could be characterized as a pandemic.⁶

¹ World Health Organization, Regional Office for the Eastern Mediterranean, Health Topics, COVID-19, About COVID-19 (www.emro.who.int/health-topics/corona-virus/about-covid-19.html) (accessed May 11, 2020).

² *Id.*

³ Press Conference with Dr. Tedros Adhanom, Director-General, World Health Organization (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 *Id.*

⁵ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19), Frequently Asked Questions (www.cdc.gov/coronavirus/2019-ncov/faq.html) (accessed May 11, 2020).

⁶ Press Conference with Dr. Tedros Adhanom, Director-General, World Health Organization (Mar. 11, 2020) (www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020).

As of May 10, according to the WHO, nearly every country in the world is reporting COVID-19 cases with over four million cases globally and over 275,000 deaths.⁷ As of May 10, according to the Centers for Disease Control and Prevention (CDC), there have been over 1.3 million cases of COVID-19 in the United States and over 79,000 deaths.⁸ The United States has the most confirmed COVID-19 cases in the world, with more than 13 times the number of cases reported in China and more than five times as many cases as Italy and Spain.⁹ Confirmed infections in the United States make up about a third of the world's coronavirus cases.¹⁰

All 50 states, the District of Columbia, and four United States territories are now reporting cases of COVID-19. Different parts of the country are seeing different levels of COVID-19 activity.¹¹ The United States nationally is in the acceleration phase of the pandemic, which means that infections are increasing.¹²

II. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

In 2006, Congress created the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness at the Department of Health and Human Services (HHS) through the Pandemic and All-Hazard Preparedness Act (P.L. 109-417) (PAHPA). BARDA was established to aid in securing our nation from chemical, biological, radiological, and nuclear threats, as well as from pandemic influenza and emerging infectious diseases. BARDA supports the research and development of medical countermeasures such as vaccines, drugs, and diagnostics, including technical assistance for purposes of review by the Food and Drug Administration (FDA) and inclusion into the Strategic National Stockpile (SNS).¹³

⁷ World Health Organization, WHO Coronavirus Disease (COVID-19) Dashboard (covid19.who.int/) (accessed May 8, 2020).

⁸ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19), Cases in the U.S. (www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html) (accessed May 11, 2020).

⁹ COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU) (gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6) (accessed May 9, 2020).

¹⁰ *Id.*

¹¹ Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19), Situation Summary (www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html) (updated Apr. 19, 2020).

¹² *Id.*

¹³ Biomedical Advanced Research and Development Authority, Home Page (www.phe.gov/about/barda/Pages/default.aspx) (accessed May 11, 2020).

In response to COVID-19, BARDA is investing in an array of medical countermeasures to diagnose, treat, or protect against the virus including respiratory protective devices, diagnostic tests or assays, vaccines, and therapeutics.¹⁴

III. FEDERAL EFFORTS TO DEVELOP AND SUPPLY COVID-19 MEDICAL COUNTERMEASURES

A. Respiratory Masks

Health care workers interacting with COVID-19 patients or suspected cases wear respiratory masks to control exposure to infections. On February 26, HHS Secretary Azar said that the SNS included 12 million N95 masks and 30 million surgical masks¹⁵ — only about one percent of the 3.5 billion masks that HHS estimates the country will need if the pandemic lasts at least a year.¹⁶

Hospitals across the country reported to the HHS Office of the Inspector General (OIG) that a shortage of Personal Protective Equipment (PPE) was threatening their ability to keep staff safe while they worked to treat patients with COVID-19.¹⁷ The most commonly needed PPE items reported were masks (including N95 masks, surgical masks, and face shields).¹⁸

On March 24, the Administration confirmed it had established a Supply Chain Stabilization Task Force to coordinate supply chain activities, including for the procurement of medical supplies such as PPE.¹⁹ On April 2, the Administration announced it would use the Defense Production Act to “use any and all authority available under the Act to acquire” N95

¹⁴ Department of Health and Human Services, Biomedical Advanced Research and Development Authority (BARDA) Broad Agency Announcement (BAA) (beta.sam.gov/opp/1b46a4169fcb4902b9c4fcb5bf981f7/view) (accessed May 8, 2020).

¹⁵ *The US has a stockpile of masks, health secretary says*, CNN (Feb. 26, 2020) (www.cnn.com/asia/live-news/coronavirus-outbreak-02-26-20-intl-hnk/h_d18cf0c9f803033ffdeff947ad1bae26).

¹⁶ *HHS Clarifies US Has about 1% of Face Masks Needed for ‘full-Blown’ Coronavirus Pandemic*, CNBC (Mar. 4, 2020) (www.cnbc.com/2020/03/04/hhs-clarifies-us-has-about-1percent-of-face-masks-needed-for-full-blown-pandemic.html).

¹⁷ U.S. Department of Health and Human Services, Office of the Inspector General, *Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020* (Apr. 2020) (https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf).

¹⁸ *Id.*

¹⁹ Press Conference with President Donald J. Trump (Mar. 24, 2020) (www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-9/).

respirators from the manufacturer 3M.²⁰ According to the Federal Emergency Management Agency, a total of 35.7 million FEMA-procured masks and respirators from the manufacturer 3M have been distributed to priority areas as of April 12.²¹

B. Diagnostic Tests

In vitro diagnostic tests, including reagents, instruments, and systems, are medical devices used to diagnose diseases or conditions, such as COVID-19.²² The first in vitro diagnostic test produced in the United States for COVID-19 was developed by the Centers for Disease Control and Prevention (CDC). After a possible contamination in CDC's test resulted in inconclusive tests, CDC had to revise its test causing a delay in access.²³ In an effort to help facilitate increased testing capacity, FDA, which regulates in vitro diagnostic tests, issued guidance on March 16 outlining how clinical laboratories, commercial manufacturers, and other entities could develop and market diagnostic tests for COVID-19.²⁴ FDA has revised this guidance since to outline the agency's enforcement policies regarding how States could authorize tests, as well as how serological tests could be marketed.²⁵ In addition, both FEMA and the Department of Defense have utilized their authorities to procure test swabs.²⁶

²⁰ The White House, *Memorandum on Order Under the Defense Production Act Regarding 3M Company* (Apr. 2, 2020) (www.whitehouse.gov/presidential-actions/memorandum-order-defense-production-act-regarding-3m-company/).

²¹ Federal Emergency Management Agency, *FEMA ADVISORY – MAY 9, 2020: Coronavirus Pandemic: Whole-of-America Response* (May 9, 2020).

²² 21 C.F.R. § 809.3 (2019).

²³ *Amid testing concerns, US officials unveil new coronavirus test kits and streamline commercial development*, CNBC (Feb. 28, 2020) (www.cnbc.com/2020/02/28/amid-testing-capacity-concerns-cdc-unveils-new-coronavirus-test-kits.html).

²⁴ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics* (Mar. 16, 2020). (www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help).

²⁵ U.S. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff* (May 11, 2020) (www.fda.gov/media/135659/download).

²⁶ U.S. Department of Defense, *DOD Details \$75 Million Defense Production Act Title 3 Puritan Contract* (Apr. 29, 2020) (www.defense.gov/Newsroom/Releases/Release/Article/2170355/dod-details-75-million-defense-production-act-title-3-puritan-contract/) (press release); Federal Emergency Management Agency, *Project Air Bridge Delivers Supplies for Nationwide Distribution* (Apr. 5, 2020) (www.fema.gov/ar/media-library/assets/images/186902) (press release).

Despite these actions, access to testing and testing supplies continues to be an issue for many health care entities. These shortages were documented by the HHS OIG which found that “severe shortages of testing supplies and extended waits for test results limited hospitals’ ability to monitor the health of patients and staff.”²⁷ Governors and public health officials have said that the shortages limit states’ ability to control the spread of the virus.²⁸

C. Therapeutics

There are currently no approved treatments for COVID-19. According to FDA, there are 72 active trials of therapeutics, and over 200 development programs are in in planning stages.²⁹ COVID-19 treatment guidelines released by the National Institutes of Health recommend that clinical management for patients diagnosed with COVID-19 should include “infection prevention and control measures and supportive care, including supplemental oxygen and mechanical ventilatory support when indicated.”³⁰ Therapeutic options being actively explored by the Administration include the use of antivirals and convalescent plasma or hyperimmune immunoglobulin.

Hydroxychloroquine and chloroquine are two antiviral drugs approved for the treatment of malaria and lupus that are being investigated for purposes of treating COVID-19. On March 28, FDA issued an emergency use authorization (EUA) for hydroxychloroquine and chloroquine to allow the drugs to be donated to the SNS and to be distributed and prescribed to COVID-19 patients under certain conditions when a clinical trial is not available or feasible.³¹ As part of the EUA, FDA noted there is limited in-vitro and anecdotal data about the use of these products for COVID-19.³²

²⁷ See note 17.

²⁸ *Testing Remains Scarce as Governors Weigh Reopening States*, The New York Times, (Apr. 25, 2020) (www.nytimes.com/2020/04/25/us/politics/virus-testing-shortages-states-trump.html).

²⁹ U.S. Food and Drug Administration, *Drugs, Emergency Preparedness | Drugs, Coronavirus (COVID-19) | Drugs, Coronavirus Treatment Acceleration Program (CTAP)* (www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap) (accessed May 11, 2020).

³⁰ National Institutes of Health, *COVID-19 Treatment Guidelines, Therapeutic Options for COVID-19 Currently Under Investigation* (www.covid19treatmentguidelines.nih.gov/therapeutic-options-under-investigation/) (accessed May 11, 2020).

³¹ Letter from RADM Denise M. Hinton, Chief Scientist, U.S. Food and Drug Administration, to Dr. Rick Bright, PhD, Director, Biomedical Advanced Research and Development Authority (BARDA) (Mar. 28, 2020) (www.fda.gov/media/136534/download).

³² *Id.*

On April 21, a panel of experts convened by the National Institute of Allergy and Infectious Diseases (NIAID) recommended against doctors using a combination of hydroxychloroquine and azithromycin for the treatment of COVID-19 patients because of potential toxicities.³³ On April 24, FDA warned that doctors should not use the chloroquine and hydroxychloroquine to treat COVID-19 patients outside a hospital or a clinical trial, citing reports of “serious heart rhythm problems.”³⁴

Remdesivir is an antiviral drug that is also being investigated for the purposes of treating COVID-19. On April 29 NIAID announced that their trial showed that remdesivir treatment led to a 31 percent faster recovery in hospital patients with COVID-19, compared with placebo treatment.³⁵

On May 1, FDA issued an EUA for remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease.³⁶ FDA noted that “while there is limited information known about the safety and effectiveness of using remdesivir to treat people in the hospital with COVID-19, the investigational drug was shown in the NIH clinical trial to shorten the time to recovery in some patients.”³⁷

IV. WHISTLEBLOWER COMPLAINT

Dr. Richard Bright is a scientist with expertise in the fields of immunology, therapeutic intervention, vaccine, and diagnostic development. Dr. Bright joined BARDA in 2010 and served as director of the agency from 2016 until April 2020. Dr. Bright claims that he was involuntarily removed from his position as Director of BARDA and transferred to the National Institutes of Health (NIH) on April 20 because of his efforts at BARDA to “prioritize science and

³³ National Institutes of Health, COVID-19 Treatment Guidelines (www.covid19treatmentguidelines.nih.gov/) (accessed May 9, 2020).

³⁴ U.S. Food and Drug Administration, Drugs, Drug Safety and Availability, FDA Cautions against Use of Hydroxychloroquine or Chloroquine for COVID-19 Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems (Apr. 24, 2020) (www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or).

³⁵ National Institutes of Health, *NIH clinical trial shows Remdesivir accelerates recovery from advanced COVID-19* (Apr. 29, 2020) (www.nih.gov/news-events/news-releases/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19) (press release).

³⁶ U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment*, (May 1, 2020) (www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment) (press release).

³⁷ *Id.*

safety over political expediency” and for other reasons.³⁸ On May 5, Dr. Bright filed a Complaint & Disclosure Form with the United States Office of Special Counsel (OSC), an independent agency, which among other things, protects federal employees from prohibited personnel practices such as whistleblowing retaliation.³⁹

On May 8, according to Dr. Bright’s lawyers, OSC made a threshold determination that HHS violated the Whistleblower Protection Act by removing Dr. Bright from his position for making protected disclosures in the best interest of the American public.⁴⁰ The Office of Special Counsel has not publicly commented on the open investigation.⁴¹ HHS has stated publicly in response to the complaint, “This is a personnel matter that is currently under review. However, HHS strongly disagrees with the allegations and characterizations in the complaint from Dr. Bright.”⁴²

V. WITNESSES

PANEL I

Richard A. Bright, Ph.D.
Senior Advisor
National Institutes of Health

PANEL II

Mike Bowen
Executive Vice President
Prestige Ameritech

³⁸ Dr. Rick Bright, Addendum to Complaint of Prohibited Personnel Practice and Other Prohibited Activity, available at ([context-cdn.washingtonpost.com/notes/prod/default/documents/6bfde4d6-4c3d-4671-8eeb-6b3d39e47c03/note/26f73d7a-d060-4c25-af4c-a58a167ee2c7.#page=1](https://www.washingtonpost.com/notes/prod/default/documents/6bfde4d6-4c3d-4671-8eeb-6b3d39e47c03/note/26f73d7a-d060-4c25-af4c-a58a167ee2c7.#page=1)).

³⁹ *Watchdog Office Says ‘Reasonable Grounds’ to Believe Ouster of Vaccine Official Was Retaliatory, His Lawyers Say*, Washington Post (May 8, 2020) (www.washingtonpost.com/health/2020/05/08/office-special-counsel-says-reasonable-grounds-believe-vaccine-officials-ouster-was-retaliatory-lawyers-say/).

⁴⁰ *Coronavirus Live Updates: F.D.A. Clears First Home Saliva Test; Pence’s Press Secretary Tests Positive*, The New York Times (May 9, 2020) (www.nytimes.com/2020/05/08/us/coronavirus-updates.html).

⁴¹ *Federal agency says removal of vaccine chief may have been retaliation*, CNN (May 8, 2020) (<https://www.cnn.com/2020/05/08/politics/richard-bright-removal-retaliation/index.html>).

⁴² *Id.*