Congress of the United States Washington, DC 20515

April 16, 2020

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

Dear Secretary Azar:

We are concerned that ideologically motivated restrictions on federally funded research utilizing fetal tissue may be blocking efforts to develop vaccines and treatments for the 2019 novel coronavirus (COVID-19). While we remain opposed to any restrictions on fetal tissue research based in ideology, it is particularly important that therapeutic research related to COVID-19 proceed without any unnecessary barriers to scientific advancement. We fear that the Administration's restrictions on the use of fetal tissue in federally funded research places ideology over science and may threaten American lives. We urge you to immediately reverse fetal tissue research restrictions on any current or future federally supported COVID-19-related research.

Since the first COVID-19 case was confirmed in the United States on January 21, 2020, there have been 632,548 confirmed cases and more than 27,012 people have died due to COVID-19 across the country. To date, the Food and Drug Administration (FDA) has not approved any vaccines or treatments for COVID-19.²

Last month, when discussing the development of COVID-19 treatments, President Trump stated: "We have to remove every barrier. There are a lot of barriers that were unnecessary... I want every American to know that we're doing everything we can." Despite this statement—and other assurances by the Administration that all avenues for preventing and treating COVID-

¹ Centers for Disease Control and Prevention, *Coronavirus Disease 2019 Cases in U.S.* (accessed Apr. 16, 2020) (www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html). *Reported confirmed cases and deaths as of April 15, 2020.*

² U.S. Food and Drug Administration, Fact Sheet for Patients and Parent/Caregivers Emergency Use Authorization (EUA) of Chloroquine Phosphate for Treatment of COVIC-19 in Certain Hospitalized Patients, (accessed Mar. 28, 2020) (www.fda.gov/media/136536/download).

³ Remarks by President Trump, Coronavirus Task Force Press Briefing (Mar. 18, 2020) (www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-6/).

19 are being pursued—the Trump Administration's restrictions on federally funded fetal tissue research already appear to be undermining efforts to develop COVID-19 therapies.⁴

For instance, COVID-19 treatment research at the National Institutes of Health (NIH) Rocky Mountain Laboratories in Montana has reportedly been on hold since February 19, 2020, when a senior government scientist asked NIH for permission to conduct COVID-19-related experiments using fetal tissue.⁵ According to public reporting, the request was forwarded to the White House's Domestic Policy Council, leaving both NIH and the Department of Health and Human Services (HHS) "waiting for a decision there." Scientists familiar with the research estimate that as many as four treatments could be tested as a result of these studies and could demonstrate effectiveness in as little as ten days.

According to HHS, for nearly a century, "the use of fetal tissue in medical research has been an instrumental component of our attempts to understand, prevent, and treat a number of conditions and diseases that affect millions of Americans." NIH has described fetal tissue as a "unique and invaluable resource for ... advancing our understanding of a wide range of conditions, and developing new treatments and cures." Research involving fetal tissue has led to the development of vaccines for numerous infectious diseases such as polio, rubella, and measles, and therapies for other infections, including HIV.

Instead of acting swiftly to lift barriers and promote the development of COVID-19-related vaccines and treatments, HHS is pushing its restrictive fetal tissue research policy

⁴ Trump ban on fetal tissue research blocks coronavirus treatment effort, Washington Post (Mar. 18, 2020) (www.washingtonpost.com/health/trump-ban-on-fetal-tissue-research-blocks-coronavirus-treatment-effort/2020/03/18/ddd9f754-685c-11ea-abef-020f086a3fab_story.html).

⁵ *Id*.

⁶ Trump ban on fetal tissue research blocks coronavirus treatment effort, Washington Post (Mar. 18, 2020) (www.washingtonpost.com/health/trump-ban-on-fetal-tissue-research-blocks-coronavirus-treatment-effort/2020/03/18/ddd9f754-685c-11ea-abef-020f086a3fab_story.html).

⁷ *Id*.

⁸ Letter from Jim Esquea, Assistant Secretary for Legislation, U.S. Department of Health and Human Services, to Ranking Member Jan Schakowsky, Select Investigative Panel on Infant Lives, U.S. House of Representatives (Apr. 6, 2016).

⁹ Letter from Francis S. Collins, M.D. PhD., Director, National Institutes of Health, U.S. Department of Health and Human Services, to Chair Marsha Blackburn, Select Investigative Panel on Infant Lives, U.S. House of Representatives (Jan. 29, 2016).

forward. In fact, you authorized additional rulemaking on this policy on February 13, 2020, two weeks after being named as lead of the President's Coronavirus Task Force. ¹⁰

The mission of HHS is "to enhance the health and well-being of all Americans…by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services." In keeping with its mission, HHS should be doing everything within its power to enable scientists to develop advances in vaccines and therapeutics.

In light of the urgent need for coronavirus vaccines and treatments, we urge you to reverse research restrictions on any studies utilizing fetal tissue conducted by government scientists and those relying on or seeking federal funding for COVID-19-related scientific research.

In addition, we request a briefing on the following topics by April 30, 2020:

- 1. The status of the Administration's decision about whether to allow the use of fetal tissue in research toward the development of vaccines and therapeutics for COVID-19;
- 2. The appeals process for researchers seeking NIH funding to support extramural research that involves use of fetal tissue and how such appeals process has been communicated to NIH scientists;
- 3. The appeals process for NIH researchers seeking to conduct intramural research that involves use of fetal tissue; and
- 4. An accounting of other appeals the Administration has received since announcing its new policy in June 2019.

¹⁰ White House, *Statement from the Press Secretary Regarding the President's Coronavirus Task Force* (Jan. 29, 2020) (press release).

¹¹ U.S. Department of Health and Human Services, *Introduction: About HHS* (accessed Mar. 27, 2020) (www.hhs.gov/about/strategic-plan/introduction/index.html).

For any questions and to arrange the briefing, please contact Jesseca Boyer and Jacquelyn Bolen with the House Committee on Energy and Commerce at (202) 225-2927, Miles Lichtman and Alexandra Golden with the House Committee on Oversight and Reform at (202) 225-5051, and Elizabeth Letter and Laurel Sakai with the Senate Committee on Health, Education, Labor, and Pensions at (202) 224-5375.

Sincerely,

Frank Pallone, Jr.

Chairman

Committee on Energy and Commerce

Carolyn B. Maloney

Chair

Committee on Oversight and Reform

Carolor B. Malony

Patty Murray

Ranking Member

Committee on Health, Education, Labor and Pensions

cc: The Honorable Greg Walden, Ranking Member House Committee on Energy and Commerce

The Honorable Jim Jordan, Ranking Member House Committee on Oversight and Reform

The Honorable Lamar Alexander, Chairman Senate Committee on Health, Education, Labor, and Pensions