Congress of the United States Washington, DC 20515

March 25, 2020

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

Dear Secretary Azar:

We are deeply alarmed that the current supply of personal protective equipment (PPE) in Oregon is inadequate to meet the urgent needs of health care workers on the frontlines of responding to the coronavirus (COVID-19) pandemic. There is clearly a national shortage of PPE, like respiratory masks, surgical gowns, and gloves. These items are required to protect health care workers and to prevent the further spread of COVID-19. We appreciate your continued work with the Congressional delegation and state officials to coordinate response efforts in Oregon and we commend the work of local health departments to distribute the limited supply of PPE to those most in need, but we remain extremely concerned that health care workers lack the necessary resources to protect their safety and well-being and that of their patients.

The United States is a hub of innovation and the supply challenges are surmountable, but it will require increased engagement from federal agencies. We urge the Department of Health and Human Services to work collaboratively with other federal agencies to help expedite the certification for non-medical manufacturers interested in producing PPE, and to provide states with clear guidance on specifications and acceptable materials.

We have heard from many companies in Oregon with the experience, facilities, equipment, and willingness to rapidly scale up manufacturing of garments and medical devices, but they are stalled by regulatory burdens. For example, we heard from one business that manufactures tools and supplies for dental practices. They contacted our offices expressing an interest in shifting their operations to produce masks and gowns, but they currently lack clarity from the federal government on the specifications, materials, and certification standards for manufacturing these products for use in responding to COVID-19. We heard from another business that supplies display products for the trade show and convention industry. With high quality fabrics on hand and sewing expertise at their disposal, they could produce surgical masks or gowns with appropriate guidance on manufacturing standards. These are only two examples of businesses across our region that are eager to help, and have the expertise, facilities, equipment, and workforce to shift production and support the PPE supply chain during this pandemic.

We urge you to consider temporary expedited evaluation and approval processes across the Food and Drug Administration, Centers for Disease Control, and National Institute for Occupational Safety and Health for companies interested in and capable of manufacturing PPE during this national emergency. Specifically, we request immediate, clear guidance from FDA, CDC, and NIOSH on the evaluation and approval processes for the manufacturing of respiratory masks, N-95 respirators, and surgical gowns.

It is unacceptable that health care workers currently lack the necessary resources to protect themselves and their patients yet are still being asked to stay on the job. Regulatory burdens in approval processes for

PPE should not exacerbate the risk exposure of workers or patients during this national emergency. Thank you for your prompt attention this matter. We look forward to continuing to work with you to make sure that our communities have the resources they need to respond to COVID-19.

Benavici Ron Wyden

Sincerely,

Suzanne Bonamici Member of Congress Ron Wyden U.S. Senator

Jeffrey A. Merkley U.S. Senator

Peter A. DeFazio Member of Congress

Earl Blumenauer Member of Congress

Greg Walden Member of Congress Kurt Schrader Member of Congress

Cc: Robert Redfield, Director of the Centers for Disease Control, Stephen M. Hahn, Commissioner of Food and Drugs, John Howard, Director of the National Institute for Occupational Safety and Health