# Congress of the United States
## Washington, DC 20510

November 10, 2022

Ambassador Katherine Tai
United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Dear Ambassador Tai:

We write to you today regarding the potential expansion of the waiver of certain obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines to also cover diagnostics and therapeutics.

We share your goal of wanting to ensure access to COVID tests and treatments around the world, including in developing countries. As the Biden Administration evaluates approaches to achieving this goal, including potentially extending the TRIPS waiver to diagnostics and therapeutics, we ask you to consider the possible unintended consequences of lessening American intellectual property (IP) protections. The United States is a global leader in research and development (R&D) and innovation partially because of our strong commitment to protecting IP. Our robust IP protections have been critical for building American pharmaceutical manufacturing facilities in the United States and supporting strong job growth in the biotech sector, as best reflected by the U.S.-based companies leading the way in vaccine, diagnostic, and therapeutic development.

We are concerned that an extension of the TRIPS waiver for COVID-related therapeutics and diagnostics will have unintended adverse consequences, such as hampering American manufacturing and shifting jobs to foreign countries. Such expansion of the TRIPS waiver may disincentivize the biotech sector from investing in R&D for products and treatments that we will need in a future pandemic or other public health crisis. Additionally, we are concerned that this effort could undermine the Biden Administration's recent launch of the National Biotechnology and Biomanufacturing Initiative, slowing growth of the biotech sector here at home. The expansion of a TRIPS waiver risks the transfer of innovative technologies and jobs to foreign countries. As you formulate the U.S. position on extending the TRIPS waiver to COVID-related therapeutics and diagnostics, please consider these possible consequences of your decision.

To advance our efforts to better understand the impacts of the TRIPS waiver as well has how you are approaching the decision to potentially extend the waiver, we respectfully request that you respond in writing to the following questions:

1. How effective has the current TRIPS waiver for COVID vaccines been in achieving the original goals established when implemented? What has been the net impact of the TRIPS waiver for COVID vaccines on access to the global vaccine supply? Please

provide us with any analysis on the impacts of the TRIPS waiver on COVID vaccine access.

2. In the context of your answer above, please share the Administration's assessment of how and why extending the TRIPS waiver to diagnostics and therapeutics might best achieve the objective of efficient, fair global access to test and treatments.

3. What, if any, data do you have on how companies are using existing systems to share IP through bilateral licensing and the UN Medicines Patent Pool? Where have these existing systems worked effectively to facilitate equitable access to therapeutics and diagnostics? Where do you believe there have been shortfalls?

4. How will you define a "diagnostic" or "therapeutic" as you consider expanding the TRIPS waiver for COVID-19 vaccines to also cover diagnostics and therapeutics?

5. What is the likely potential impact of an expansion of the TRIPS waiver on the American manufacturing industry and future R&D investment in vaccines, therapeutics, and diagnostics, including those unrelated to COVID-19? Please provide any analytical backup to support this assessment.

6. How is the impact on American industry outweighed by the expected benefit of expanding the waiver to diagnostics and therapeutics? How, if at all, will American businesses adversely affected by such an expansion be compensated?

7. Please provide a list of countries that have expressed interest in gaining access to American IP for COVID diagnostics and therapeutics.

As you consider taking a position on this matter, we hope to continue to be partners with you. We thank you for your hard work and look forward to your response.

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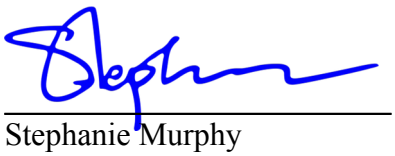
Sincerely,

Bradley Scott Schneider
Member of Congress

Jim Cooper
Member of Congress

J. Luis Correa
Member of Congress

Ron Kind
Member of Congress



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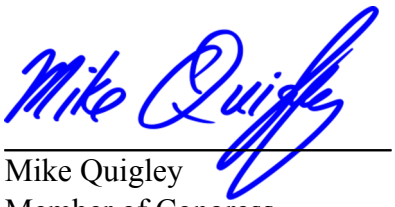
Member of Congress

Stacey E. Plaskett
Member of Congress



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Member of Congress

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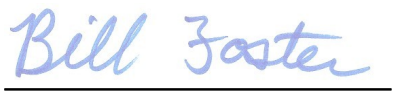
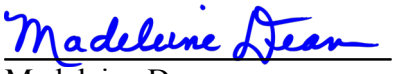
Member of Congress



Bill Foster
Member of Congress



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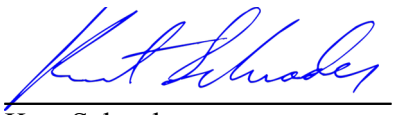
Member of Congress

Scott H. Peters
Member of Congress



Kurt Schrader
Member of Congress

Deborah K. Ross
Member of Congress