Please Extend the WTO TRIPS Decision to Treatments and Tests and Support Countries Using WTO Flexibilities to Access COVID-19-Related Medical Technologies

August 23, 2022

Dear President Biden:

As health, labor, consumer, human rights, development and other organizations we write to urge you to take steps to ensure intellectual property (IP) barriers do not stand in the way of controlling the COVID-19 pandemic, including by promptly endorsing extension of the June 17 World Trade Organization (WTO) Decision on the TRIPS Agreement to cover treatments and diagnostic tests, and supporting countries using all available WTO IP flexibilities.

The United States and the rest of the world continue to suffer COVID-19 infection spikes as yet more transmissible variants emerge. With only about 20% of people in low-income nations vaccinated, preventable deaths and economic devastation continue, as do outbreaks that allow the virus to continue to mutate, which contributes to waning vaccine protection against infection.

Despite limitations, we are fortunate to have not only vaccines, but also effective outpatient antivirals. These medicines are widely distributed in the United States under your signature Test-To-Treat Program. The critical importance of therapeutics is underscored by significant advance purchases of both molnupiravir (3.1 million courses of treatment) and Paxlovid (20 million courses) for use in the United States. However, few doses are available to even the highest risk patients in low- and middle-income countries. While America and other high-income countries account for nearly all supply deals of Paxlovid, the most strongly recommended antiviral, reports from the ACT-Accelerator indicated that almost no doses of any outpatient antivirals have been yet purchased by low- and middle-income countries. Such countries are lagging in planning for robust test-and-treat programs because of uncertainty about supply, affordability, and equitable distribution of COVID-19 therapeutics. In some middle-income countries Pfizer has reportedly quoted prices of $250 per treatment course of Paxlovid – 10 times more than the $25 price available to eligible lower-income countries covered by the Pfizer-Medicines Patent Pool license.

We were therefore deeply disappointed that a comprehensive IP waiver, which could have enabled greater access to affordable COVID-19 medical tools for all who need them, was not agreed at the mid-June WTO Ministerial. Instead, the June 17, 2022 WTO Decision on the TRIPS Agreement largely restates the WTO's existing flexibilities that allow countries to issue compulsory licenses on medical tools while adding some new limitations. While the June 17 Decision could make it easier for countries to export vaccines made under compulsory licenses, it does not apply to the COVID-19 treatments and tests that would be easiest to produce under such licensing. However, the text requires countries to decide whether to extend it to those medical products "no later than six months from the date of the Decision."

We urge you to immediately announce U.S. support for extending the June 17 WTO Decision on the TRIPS Agreement to treatments and diagnostic tests mutatis mutandis (without further changes). Doing so can help prevent needless disease progression and death from SARS-COV-2, by enabling countries (especially those middle-income countries excluded

from voluntary licenses) to establish additional sources of supply of COVID-19 medicines from authorized manufacturers that could thereafter export any quantities needed to Decision-eligible countries that remove patent and data-related barriers (if any). Immediate U.S. support will make the difference in the June 17 WTO TRIPS decision being extended to diagnostics and therapeutics.

We also urge you to announce U.S. support for countries using the WTO flexibilities. This should include a pledge that the U.S. government will not pressure or threaten countries who do adopt or use WTO flexibilities, file trade enforcement cases against them at the WTO or under U.S. free trade agreements (FTA), list such actions in the annual "Special 301" report, or otherwise threaten trade sanctions, withdrawal of trade preferences, or any other diplomatic or trade pressure to deter countries from adopting or using such TRIPS-compliant measures. There is ample precedent for the U.S. government formally announcing such a policy, such as President Clinton's Executive Order 13155 (May 10, 2000) on Access to HIV/AIDS Pharmaceuticals and Medical Technologies. The U.S. should also withdraw consent to Investor-State Dispute Settlement (ISDS) challenges related to access to COVID-19 medicines and medical tools so pharmaceutical corporations cannot use U.S. FTAs and investment treaties to attack such measures. While you pledged not to include the extreme ISDS mechanism in new agreements you may negotiate, it is critical to withdraw consent to stop the serious threat posed by ISDS in existing pacts.

As the U.S. has experienced firsthand with its incorporation of government-use license provisions at least 59 times in COVID-19-related procurement contracts, government use/ compulsory licenses are an important WTO flexibility. We urge the administration to publicly clarify that it does not oppose issuance of similar TRIPS-compliant compulsory licenses on COVID-19-related medical tools in general and specifically with respect to compulsory licensing efforts in the Dominican Republic, Colombia, Peru and Chile on Pfizer's outpatient COVID-19 antiviral, Paxlovid. In addition, the U.S. should formally clarify and declare, consistent with the May 2007 Trade Policy Declaration, that any relevant regulatory data protection rule shall not prevent the regulatory approval or emergency use listing of an equivalent COVID-19-related medical technology whether or not a compulsory license has been issued.

At the Second Global Summit, the U.S. and other governments affirmed the need to prevent needless human suffering by expanding and resourcing test-and-treat programs worldwide. More than two months later as IP barriers contribute to persistent vaccine inequities and similar patterns of inequity in test-and-treat programs, the time to act is now.

Sincerely,

American Federation of Teachers
American Friends Service Committee
American Jewish World Service
Amnesty International USA
Association of Flight Attendants-CWA
Campaign for America's Future
Center for Science in the Public Interest

Chronic Illnesses Advocacy & Awareness Group
Citizens Trade Campaign
Coalition of Labor Union Women
Demand Progress
Doctors Without Borders / Médecins Sans Frontières USA
Greenpeace USA
Health Advocacy International
Hip Hop Caucus
Holy Cross International Justice Office
Human Rights Watch
Indivisible
Initiative for Medicines, Access & Knowledge (I-MAK)
Justice is Global
Knowledge Ecology International (KEI)
Latin America Working Group (LAWG)
Maryknoll Office for Global Concerns
MoveOn
National Association of Consumer Advocates
National Organization for Women
Our Revolution
Oxfam America
Presbyterian Church (USA)
Pride at Work
Public Citizen
R2H Action [Right to Health]
Rethink Trade
Right to Health Access
The United Methodist Church - General Board of Church and Society
Trade Justice Education Fund
Unitarian Universalists for a Just Economic Community
United Brotherhood of Carpenters
United Electrical, Radio & Machine Workers of America (UE)
United States Catholic Mission Association
Washington Office on Latin America (WOLA)

cc. The Honorable Katherine Tai
United States Trade Representative

The Honorable Ashish Jha Coordinator of
COVID-19 Response and Counselor to the President

The Honorable Jacob Sullivan
Assistant to the President for National Security Affairs

The Honorable Brian Deese
Director National Economic Council

The Honorable Antony Blinken
Secretary of State

The Honorable Gina Raimondo
Secretary of Commerce