March 20, 2018

The Honorable Robert Lighthizer
United States Trade Representative
Executive Office of the President
600 – 17th Street, NW
Washington DC 20508

RE: U.S. Government Pressure on Colombia in Light of OECD Accession

Dear Ambassador Lighthizer:

We write to you to raise concerns about pressures in recent months from your office, which reflect similar pressure from the U.S. Chamber of Commerce (the Chamber) and others, on the government of Colombia to curtail measures undertaken to increase access to affordable medicines for its citizens. This undue pressure undermines Colombia's legitimate use of the flexibilities enshrined in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). We urge you to stop promoting the interests of pharmaceutical companies even at the expense of people's health in Colombia.

We specifically refer to your letter to Minister Gutiérrez of February 14, 2018[1] on behalf of "specific stakeholders," requesting that Colombia undertake a "focused and sustained outreach and listening campaign to address, where possible, industry concerns" including pharmaceutical-related provisions of Colombia's National Development Plan (NDP), as a precursor to U.S. support for Colombia's accession to the Organization for Economic Co-operation and Development (OECD).

This Office of the United States Trade Representative (USTR) letter follows the 2018 submissions of the Pharmaceutical Research and Manufacturers of America (PhRMA),[2] the Biotechnology Innovation Organization (BIO),[3] the National Association of Manufacturers (NAM),[4] and the Chamber[5] to the USTR Special 301 in which these groups called for Colombia to be placed on the Priority Watch List and given an Out-of-Cycle Review. The reasons in large part were regulatory and legal measures that Colombia has taken to protect public health, such as the price reduction of imatinib, a leukemia medicine (marketed by Novartis as Glivec) in

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[1] https://www.keionline.org/wp-content/uploads/2018/03/Lighthizer-letter-to-Colombia-Feb-14-2018-re-OECD.pdf
[2] https://www.keionline.org/wp-content/uploads/2018/02/PhRMA_2018_Special_301_Submission.pdf
[3] https://www.keionline.org/wp-content/uploads/2018/02/2018_BIO_301_Submission_Final.pdf
[4] https://www.keionline.org/wp-content/uploads/2018/02/NAM_2018_Special_301_Comments_FINAL.pdf
[5] https://www.keionline.org/wp-content/uploads/2018/02/2_8_Final_2018_U_S_Chamber_Special_301_Submission.pdf

2016, and to enable a biosimilar pathway to promote competition in the highly uncompetitive and high priced biologic pharmaceutical market.

USTR's actions demonstrate that the United States has a double standard with respect to the government's efforts to deal with the global epidemic of high drug prices, including the non-voluntary use of patented inventions, given the variety of statutes in U.S. law providing the right of the government to make non-voluntary use of patents.[6]

Furthermore, high prices of medicines remain at the top of Americans' priorities in poll[7] after poll.[8] The United States, as with many other OECD countries, is in the midst of long overdue debate on legislation and policies that should be enacted to make medicine affordable for all. Some of this debate includes how to further expedite market entry of biosimilars in light of the particularly high costs of many biologic medicines. There are a number of proposed bills that would

[6] These statutes include: the government use provisions of 28 U.S.C. § 1498, used frequently by the military and recently the subject of a request by Representative Khanna and seventeen other members of the House of Representatives to use that authority for HCV drugs; the march-in rights of the Bayh-Dole Act (35 U.S.C. § 203), the subject of a petition for the expensive prostate cancer medicine enzalutamide (marketed by Astellas as Xtandi) in 2016 that is likely to be revisited in light of a recent Directive by the Senate Armed Services Committee (115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, page 173: **Licensing of federally owned medical inventions.** *The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.*); compulsory licensing remedies used in the context of antitrust actions including both merger reviews and enforcement actions by the Department of Justice and the Federal Trade Commission on everything from tow truck patents, clean fuel patents, and patented software, to seeds and new drugs; and specialized statutes including sections within:

- The Clean Air Act (42 U.S.C. § 7608 - Mandatory Licensing)
- The Atomic Energy Act (42 U.S.C. § 2183 - Nonmilitary Utilization)
- The United States Energy Storage Competitiveness Act of 2007 (42 U.S.C. §17231 - Energy Storage Competitiveness)
- The Energy Policy Act (42 U.S.C. § 16192 - Next Generation Lighting Initiative)
- The Mine Safety and Health Act (30 U.S.C. § 937 - Contracts and Grants [Black Lung Disease])
- The Smoot-Hawley Tariff Act (19 U.S.C. § 1337 - Unfair Practices in Import Trade)
- The Patent Act (35 U.S.C. § 271 - Infringement of Patent [involving patents for biologic drugs as specified in the Affordable Care Act])

Additionally, the United States patent law under 35 U.S.C. § 283 provides courts the right to deny permanent injunctions in patent infringement cases, and courts have used this authority to grant compulsory licenses on medical technologies.

[7] https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/

[8] https://www.politico.com/story/2017/09/25/politico-harvard-poll-congress-should-focus-on-reducing-drug-prices-243109

expedite biosimilar entry, including bipartisan legislation in the CREATES Act,[9] as well as the PRICED Act,[10] which would reduce the number of years of exclusivity for biologics. In September 2017, The Food and Drug Administration issued draft guidance to facilitate entry of biosimilars into the marketplace.[11] With the high prices of biologic medicines creating problems for patients, payers, and health budgets even within the United States, the USTR should not be siding with the pharmaceutical industry in pressuring Colombia against introducing solutions that the United States itself may soon be considering.

Many other countries are also facing strong difficulties with medicines' prices.[12] As you are aware, the problem of access to medicines was recognized as a global issue by the United Nations Secretary-General's High-Level Panel on Access to Medicines (HLP), and a number of OECD member countries are considering various measures to tackle high prices of medicines. For instance, Chile's congress approved the use of compulsory licensing to increase access to hepatitis C drugs, and its Ministry of Health recently announced that there are sufficient public health justifications to support a compulsory license on hepatitis C medicines.[13] In Europe, The Netherlands has made recent recommendations for firm action to address access and affordability, including through the use of compulsory licenses.[14]

As you are aware, the United States and the pharmaceutical industry were heavily criticized for undue pressures to derail Colombia's legal efforts to lower the price of the expensive drug Glivec in 2016, including through threats to withhold funds designated for the Colombian Peace Process. The criticism of these pressures was noted in many domestic and international

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[9] S. 974. https://www.congress.gov/bill/115th-congress/senate-bill/974?q=%7B%22search%22%3A%5B%22S.+974%22%5D%7D&r=1

[10] S. 3094. https://www.congress.gov/bill/114th-congress/senate-bill/3094/text

[11] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM576786.pdf

[12] World Health Organization, Progress Report on Access to hepatitis C Treatment: Focus on overcoming barriers in low- and middle-income countries, WHO/CDS/HIV/18.4, March 2018. http://www.who.int/hepatitis/publications/hep-c-access-report-2018/en/

[13] https://www.keionline.org/27163

[14] The Council for Public Health and Safety, "Development of new medicines: Better, Faster, Cheaper," Nov. 2017. Available at: https://www.raadrvs.nl/uploads/docs/Recommendation_Development_of_New_Medicines.pdf; Ellen 't Hoen, "Medicines Excitement in the Netherlands – New Health Minister announces firm action on 'absurd' medicines pricing and gets the European Medicines Agency," Medicines Law & Policy, Nov. 24, 2017. Available at: https://medicineslawandpolicy.org/2017/11/medicines-excitement-in-the-netherlands-new-health-minister-announces-firm-action-on-absurd-medicines-pricing-and-gets-the-european-medicines-agency/

publications, as well as by elected officials within the United States,[15] and by the HLP, which stated:

> Political and economic pressure placed on governments to forego the use of TRIPS flexibilities violates the integrity and legitimacy of the system of legal rights and duties created by the TRIPS Agreement, as reaffirmed by the Doha Declaration. This pressure undermines the efforts of states to meet their human rights and public health obligations.[16]

The HLP recommended that such pressures be reported to the WTO Secretariat during the Trade Policy Review of Members in order that punitive measures be applied against offending Members.

Lastly, the public health measures undertaken by the Colombian government that have raised the concerns of "U.S. stakeholders" — such as attempting to use TRIPS public health safeguards, implementing the requests of the World Health Organization Resolution WHA67.21 on access to biologic medicines and addressing high prices of medicines — are fully consistent with international agreements such as TRIPS and the Doha Declaration and also with OECD's mission of "promoting policies that will improve the economic and social well-being of people around the world." It is fully incoherent for the U.S. government to condition the support of Colombia in its intention to become a member of the OECD on prioritizing pharmaceutical companies' trade interests over public health needs. As an OECD member, the U.S. government is expected to promote development of policies by other countries that benefit rather than threaten people's health.

We therefore strongly urge the U.S. government to cease all pressure and demands on the government of Colombia or any other country to stop use of measures, including the use of TRIPS flexibilities to promote competition, that can improve access to affordable medicines for their population.

We would welcome the opportunity to discuss this matter further with you at your convenience.

Sincerely,

Acción Internacional para la Salud, Peru
Alianza LAC-Global por el Acceso a Medicamentos

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[15] *See* Letter from Sen. Sherrod Brown and Sen. Bernie Sanders to Michael Froman, May 26, 2016. Available at: https://www.keionline.org/wp-content/uploads/Senate-Colombian-Compulsory-License-May-26-2016.pdf; Letter by Rep. Sander Levin, *et al*, May 25, 2016. Available at: https://democrats-waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/Colombia%20Compulsory%20License%20Letter.pdf

[16] Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, p.8.

Canadian HIV/AIDS Legal Network
Center of Medicines Information of the National University of Colombia
Coalition PLUS
The Colombia Bishop Conference
Colombian Medical Federation
Committee of Oversight and Cooperation in Health (Colombia)
Doctors Without Borders/Médecins Sans Frontières USA
Franciscan Action Network
Fundación IFARMA (Colombia)
Global Health Justice Partnership (Yale Law / Yale School of Public Health)
Global Justice Now
Health Action International
Health GAP
International Treatment Preparedness Coalition Latin American and Caribbean ITPC-LATCA
Knowledge Ecology International
Medicines Observatory of Colombian Medical Federation (OBSERVAMED)
Misión Salud (Colombia)
Northwestern Pritzker School of Law International Human Rights Clinic
Oxfam America
People of Faith for Access to Medicines
Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
Public Citizen
Public Eye
Salud por Derecho (Spain)
Salud y Farmacos - USA
Stop AIDS
Third World Network
Treatment Action Campaign
Treatment Action Group
The Union for Affordable Cancer Treatment
Universities Allied for Essential Medicines

Cc:
Minister María Lorena Gutiérrez, Colombia Ministry of Commerce, Industry, and Tourism
Minister Alejandro Gaviria Uribe, Colombia Ministry of Health and Social Protection

Secretary Alex Azar, United States Department of Health and Human Services

Ms. Catalina Crane, High Level Contact - Colombia's OECD Accession Process
Mr. Angel Gurría, Secretary-General of the OECD