March 14, 2018

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

RE: USTR Pressure on Colombia in Light of OECD Accession

Dear Ambassador Lighthizer:

We write to express opposition to pressures in recent months from the office of the United States Trade Representative, the Pharmaceutical Research and Manufacturers of America (PhRMA), the National Association of Manufacturers (NAM), the Biotechnology Innovation Organization (BIO), and the U.S. Chamber of Commerce, urging Colombia to curtail activities to increase access to affordable medicines for its citizens.

Specifically, in the last two months we are aware of: (1) one letter from PhRMA[1] attacking Resolution 5246 of December 20, 2017, which allows the Ministry of Health to study whether there is sufficient evidence to support a declaration that compulsory licenses on medicines for hepatitis C virus (HCV) are in the public interest, and intimating that continuing down this path could threaten Colombia's OECD accession; (2) the 2018 submissions of PhRMA[2], BIO[3], NAM[4] and the Chamber[5] to the USTR Special 301 in which PhRMA, BIO and NAM called for Colombia to be placed on the priority watch list and given an out-of-cycle review in large part due to regulatory and legal measures Colombia has taken to protect public health, such as the price reduction of Glivec in 2016, and Colombia's abbreviated biosimilar pathway; and, subsequently, (3) your letter to Minister Gutiérrez of February 14, 2018[6], requesting, on behalf of "specific stakeholders" 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 OECD.

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[1] Letter from Brian Toohey, PhRMA, to Minister Alejandro Gaviria, Jan. 15, 2018. Available at: https://www.keionline.org/wp-content/uploads/2018/01/PhRMA-Comments-on-Colombia-Resolution-5246.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

[6] https://www.keionline.org/wp-content/uploads/2018/03/Lighthizer-letter-to-Colombia-Feb-14-2018-re-OECD.pdf

It is fair to suggest that the United States has a double standard as regards 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. 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[7] 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[8] which is likely to be revisited in light of a recent Directive by the Senate Armed Services Committee[9]; 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.[10]

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[7] https://khanna.house.gov/sites/khanna.house.gov/files/Final%20Letter%20-%20signed.pdf
[8] https://www.keionline.org/xtandi
[9] 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.

[10] https://www.keionline.org/misc-docs/events/running-royalties-5jul2017.pdf

Furthermore, high prices of medicines remain at the top of Americans' priorities in poll[11] after poll[12]. The United States, as with many other OECD countries, is in the midst of heated 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 expedite biosimilar entry, including bipartisan legislation in the CREATES Act[13], as well as the PRICED Act[14], which would reduce the number of years of exclusivity for biologics. In September 2017, The Food and Drug Administration, under the Trump Administration, issued draft guidance to facilitate entry of biosimilars into the marketplace.[15] 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 for working towards solutions that the United States itself may soon be considering.

Lastly, 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 leukemia medicine imatinib (marketed by Novartis as 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 publications, as well as by elected officials within the United States[16], and by the United Nations Secretary General's High-Level Panel on Access to Medicines (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. [17]

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

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

[13] 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

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

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

[16] *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

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

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

We request that the coming Special 301 Report supports Colombia's efforts to increase access to affordable medicines, and request a meeting to discuss this matter further.

Sincerely,

United States
Health GAP
Knowledge Ecology International
Doctors Without Borders/Médecins Sans Frontières USA
Oxfam America
Public Citizen

Colombia
Alianza LAC-Global por el Acceso a Medicamentos
Center of Medicines Information of the National University of Colombia
The Colombia Bishop Conference
Colombian Medical Federation
Committee of Oversight and Cooperation in Health
La Fundación IFARMA
Medicines Observatory of Colombia (OBSERVAMED)
Misión Salud