

July 20, 2016

The Honorable Secretary of State John F. Kerry
U.S. Department of State
2201 C Street, N.W.
Washington, D.C. 20520

Dear Secretary Kerry:

We are writing to express our concern about recent statements made by representatives of the State Department on issues regarding intellectual property (IP) and access to medicines in various settings, including proceedings in Colombia, several important United Nations fora, and in India.

Colombia & Cancer Treatments

In May 2016, leaked memos from the Colombian Embassy suggested that the United States Trade Representative and others in the United States government and Congress have pressured the government of Colombia not to increase affordable access to imatinib, a leukemia drug marketed by Swiss company Novartis under the brand names Gleevec or Glivec. The drug has generated over \$47 billion in global sales for Novartis and already faces generic competition in the United States. The Novartis price for the drug in Colombia per patient is approximately twice the Colombian gross national income (GNI) per capita.

The government of Colombia has been asked by Colombian civil society organizations to issue a compulsory license on the patents, in compliance with the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in order to remove barriers to generic competition and to foster affordable access to this lifesaving drug.

The Colombian Embassy was sufficiently alarmed by the pressure from the United States to twice remark that it was concerned that proceeding with the compulsory license would put at risk the \$450 million committed for President Obama's initiative to support the Colombian peace process, *Paz Colombia*.

More recently, following a public announcement on June 9 by the Minister of Health that he would proceed with a public interest declaration to lower the price of the drug — only one of a series of enumerated steps toward a compulsory license under Colombian law — news outlets aired footage of United States Ambassador to Colombia Kevin Whittaker publicly stating that it is very important for the Colombian government to consult with the United States on this decision.¹

¹ Whittaker's comments may be viewed here, at the 12:20 mark:
<https://www.youtube.com/watch?v=2sEHVOV1hPs>

The declaration by the Minister was the result of over a year and a half of national consultations, and follows Novartis's complete rejection of efforts by the Colombian Ministry of Health to negotiate a more affordable price.

We were surprised and dismayed by Ambassador Whittaker's remarks, which were interpreted, in Colombia and elsewhere, as unwanted interference with a domestic dispute over the price of a drug sold by the Swiss corporation. The United States State Department should not interfere with the government of Colombia's efforts to increase access to affordable medicines. Colombia is under no obligation to consult the United States on a decision to use its national law, when its actions are consistent with trade agreements binding both the United States and Colombia.

United Nations (UN) Secretary General's (SG) High-Level Panel on Access to Medicines

In November 2015, UN Secretary General Ban Ki-Moon announced the convening of a High-Level Panel on Access to Medicines (HLP) "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."² The call for submissions for consideration of the HLP to inform its report welcomed participation from a wide array of organizations from a diverse collection of sectors including governments, industry, civil society, academia, and intergovernmental organizations. The panel itself consists of former heads of state, academics, generics and brand-name pharmaceutical industry leaders, treatment activists, civil servants and more.

We are troubled by public statements from United States State Department representatives regarding the mandate, composition and work of the HLP, including in its official submission to the panel, labeling it as possessing a "critical flaw." The U.S. submission went so far as to question the very premise of the panel, namely that a conflict exists between "the rights of inventors, international human rights law, trade rules, and public health."³ Such a sentiment is out of touch with the reality faced every day by patients in developing countries around the world and here in the United States faced with rising drug prices and lack of innovation for critical medical needs, such as antibiotic resistance and Zika.

In June 2016, the U.S. Mission to the United Nations criticized the HLP again in its statement at the UN High Level Meeting on Ending AIDS. The U.S. Mission cited amongst its concerns "the Panel's narrowly-defined mandate, the non-transparent manner in which it was constituted, and the presumption of a policy incoherence."⁴

We are deeply disappointed that the U.S. has expressed these views. Most disturbing was the fact that the U.S. mission questioned the notion of policy incoherence. This incoherence is both

² <http://www.unsgaccessmeds.org/the-process/>

³ <http://www.unsgaccessmeds.org/inbox/2016/2/27/united-states-department-of-state>

⁴ <http://usun.state.gov/remarks/7321>

straightforward and important. Policies that lead to higher prices create barriers for access. If governments rely upon high prices to fund innovation, then they have to accept limited and unequal access to new medicines, as well as no innovation when high prices through sales are not an option to recover R&D costs. In what sense does the Department of State see that as coherent and good policy?

The work of the UN HLP on Access to Medicines to advance conversations to remedy this policy incoherence is vital. The challenges caused by high prices of medicines and lack of innovation are not a developing country concern only and should become a global priority, as the G7/G20 and the UN is increasingly recognizing through the search for strategies to better respond to antimicrobial resistance.

India

We are concerned about the growing evidence that the United States continues to place pressure on the Government of India to adopt policies that result in higher drug prices and the elimination of production sources of affordable generic drugs. These pressures including attacks on India's use of compulsory licensing of patents on drugs that are not affordable, and efforts to change India's law on the granting of patents that expand, extend and "evergreen" drug monopolies.

The U.S. State Department has played an active role in this pressure: the U.S. Embassy in New Delhi regularly provides a forum for industry representatives to address Indian policymakers and stakeholders,⁵ works with the U.S. Patent and Trademark Office's Intellectual Property Rights Attachés to coordinate pressure on key officials, and delivers speeches designed to publicly push the Indian government to adopt restrictive IP policies.⁶ The Embassy also readily misinterprets requirements in the TRIPS agreement related to the protection of test data to argue that India should implement test data exclusivity measures.⁷

India's patent laws are compliant with the obligations and public health safeguards in the TRIPS Agreement. Even without the U.S. pressure, the WTO rules are severe and have limited the supply of affordable generic versions of most new drugs. The pressure from the U.S. seeks to go even further in limiting the supply of affordable generic medicines by preventing India from using provisions in its national law that facilitate expedited generic competition, including through the use of compulsory licenses. While these provisions are consistent with WTO rules, they are opposed by large pharmaceutical companies that seek to expand monopolies and raise drug prices worldwide.

⁵ For example, see:

<https://www.linkedin.com/pulse/us-embassy-new-delhi-invites-gavin-intellectual-property-gavin>.

⁶ <http://newdelhi.usembassy.gov/sr062716.html>.

⁷ <http://newdelhi.usembassy.gov/iprdataprot.html>.

Any policies or practices that India adopts to expand patent rights on medicines, restrict the use of compulsory licensing or other exceptions to patent rights, or introduce new exclusivity rules for data would have dramatic and negative implications for people across the globe that desperately need access to affordable life-saving medicines, including many global health programs funded by the United States government, such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Moreover, the same maximalist IP policies that the U.S. is promoting abroad are resulting in a growing and unsustainable crisis of unaffordable medicine prices right here in the United States.

We request that State Department refrains from further pressuring countries and the UN Secretary General High Level Panel on Access to Medicines.

We take note of the official U.S. government position as stated in the United States Trade Representative 2016 Special 301 Report, that “the United States respects a trading partner’s right to protect public health and, in particular, to promote access to medicines for all,” and “the United States respects its trading partners’ rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement.” We contend that the incidents described in this letter contravene this U.S. government policy.

We await your written response to this letter (a) detailing whether the State Department sees these incidents as coherent with U.S. government policy; and (b) clarifying State Department commitments and position on the right of governments to use TRIPS flexibilities to protect public health and access to medicines. Please address how the State Department will prevent recurrences of this conduct in the future, including any guidance that might be provided to U.S. government personnel.

We are available for a meeting at your earliest convenience to discuss these issues in greater detail and ensure policy coherence and fulfillment of international commitments with State Department interventions.

Sincerely,

African Services Committee
Alianza LAC-Global por el Acceso a Medicamentos
All-Ukrainian Network of People Living with HIV/AIDS
American Federation of Labor and Congress of Industrial Organizations (AFL–CIO)
American Medical Student Association
The Berne Declaration
BUKO Pharma-Kampagne
Canadian HIV/AIDS Legal Network
Cancer Families for Affordable Medicine
Catholics in Alliance for the Common Good
Center for Policy Analysis on Trade and Health (CPATH)

Center for Study of Responsive Law
Centro de Información de Medicamentos de la Universidad de Colombia (CIMUN)
Comité de Veeduría y Cooperación en Salud (CVCS)
Comunicación Positiva
Prof. Carlos Correa
Essential Information
Foundation for Integrative AIDS Research
Fundación IFARMA
Health Action International (HAI)
Health Global Access Project (Health GAP)
Initiative for Medicines, Access & Knowledge (I-MAK)
Interfaith Center on Corporate Responsibility (ICCR)
International Human Rights Clinic, University of Chicago Law School
Just Foreign Policy
Karisma Foundation
KELIN
Knowledge Ecology International
La Conferencia Episcopal de Colombia
Latin America Working Group (LAWG)
LWC Policy Consulting
Maryknoll Office for Global Concerns
Médecins Sans Frontières/ Doctors Without Borders (MSF USA)
Medicines Law & Policy
Mesa de ONGs con Trabajo en VIH/SIDA
Misión Salud
Dr. Suerie Moon
National Physicians Alliance
NETWORK Lobby for Catholic Social Justice
Observatorio del Medicamento de la Federación Médica Colombiana (OBSERVAMED)
OXFAM
Pax Christi International
Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
Prescription Justice Action Group
Presbyterian Church (USA)
Public Citizen
Prof. Susan Sell, George Washington University
Student Global Access Campaign (SGAC)
Union for Affordable Cancer Treatment
United Church of Christ, Justice and Witness Ministries
Universities Allied for Essential Medicines (UAEM)
Dr. Germán Velásquez, Former Director of the WHO Secretariat on Public health, Innovation and Intellectual property
Washington Office on Latin America (WOLA)

Yale Global Health Justice Partnership
Young Professionals Chronic Disease Network
Prof. Peter K. Yu