DON'T TRADE AWAY HEALTH
AN OPEN LETTER TO THE NORTH AMERICAN LEADERS' SUMMIT

President Barack Obama
The White House
1600 Pennsylvania Avenue
Washington, DC 20500
United States of America

Lic. Enrique Peña Nieto
Casa Miguel Alemán
Col. San Miguel Chapultepec
C.P. 11850, México DF
México

The Right Hon. Justin Trudeau
Office of the Prime Minister
80 Wellington Street
Ottawa, ON K1A 0A2
Canada

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27 June 2016

Dear Prime Minister Trudeau, President Obama and President Peña Nieto:

Re: Access to Medicines and the Trans-Pacific Partnership (TPP) Agreement

As civil society organizations concerned about access to medicines, in your three countries and globally, we write to you in advance of your North American Leaders' Summit in Ottawa on June 29. The summit is an important opportunity to demonstrate human rights leadership—nationally, regionally and globally—in the Americas.

In February of this year, the United States, Canada and Mexico all became signatories to the Trans-Pacific Partnership (TPP), one of the largest trade and investment agreements in history. Our countries now face a two-year period of time in which to consider whether or not to pursue ratification. We are deeply concerned by significant human rights shortcomings associated with the deal, particularly with regard to access to medicines. Our concerns have been echoed by UN human rights experts and numerous civil society groups in all twelve TPP member states.

The TPP threatens to undermine the protection and promotion of a range of human rights. In practice, the intellectual property chapter will undermine the ability of some of the world's poorest people to gain access to more affordable medicines. Under the TPP, individuals, public health systems and insurance providers will have to spend more to purchase drugs. Many of the world's poorest will not be able to afford them, and many will suffer ill-health or death as a result.

All States should undertake comprehensive, independent, impartial human rights impact assessments prior to concluding any new trade or investment agreements and once brought into force, at regular intervals thereafter. The UN Guiding Principles on Business and Human Rights, ratified by all members of the UN Human Rights Council in 2011, recognize that "States must protect against human rights abuse within their territory and/or jurisdiction by third parties, including business enterprises. This requires

taking appropriate steps to prevent, investigate, punish and redress such abuse through effective policies, legislation, regulations and adjudication."[1] States have an obligation to ensure that human rights are not abused in the context of trade and investment.

If adopted in its current form, the TPP would end up being the most harmful trade agreement ever for access to medicines. The provisions of the TPP go far beyond existing international agreements in their impact on access to medicines—including the WTO *Agreement on Trade-Related Aspects of Intellectual Property* (TRIPS) and the flexibilities ostensibly preserved therein for countries to make policy in the public interest such as "promoting access to medicines for all". These flexibilities were unanimously reaffirmed by WTO Members in their 2001 "Doha Declaration." Yet adopting the "TRIPS-plus" provisions currently found in the TPP would set back commitments your three countries have already made to promote global health and undermine access to medicines around the world, particularly as the TPP is being billed as a model for future international trade agreements.

North Americans—and people needing life-saving medicines in other TPP negotiating states—expect and deserve better. On June 29, human rights protection must not only be on your agenda but should, in fact, drive your agenda. The North American relationship must be one that is characterized by a firm commitment to human rights, both in how each of your governments governs its own affairs, but also in the initiatives that you pursue in common. We urge each of you to take advantage of the upcoming meeting to establish that vision of North America.

As the Trilateral Summit approaches, we write to you to express our deep concerns with numerous provisions included in the *intellectual property*, *pharmaceutical pricing* and *investment* chapters of the TPP, which raise issues of vital importance to the citizens of our three countries. At this critical juncture, we wish to outline for you a number of specific concerns about how the provisions in the TPP will undermine equitable access to affordable medicines.

1. Stricter rules on intellectual property

First, the chapter on intellectual property would strengthen and prolong the private monopoly rights enjoyed by pharmaceutical companies in various ways, impeding and delaying the competition that brings medicine prices down:

- Expanding the scope of patenting: Patents of twenty years (at least) must be available for new uses of known drugs and new methods or processes of using a known drug, even if there is no therapeutic benefit for patients—making it easier for companies to "evergreen" their patents to extend their market monopolies.

- Patent term extensions: The TPP would also require countries to extend drug companies' patent terms by years, to "compensate" them for delays in the process of getting their patent approved or getting approval to market their drug.

[1] General Assembly, United Nations, Report of the Special Representative of the Secretary General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, "Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework," Human Rights Council, Seventeenth session, 21 March 2011, UN Doc. A/HRC/17/31.

- Patent "linkage": TPP countries must create laws that give patented drug companies an opportunity to get an order blocking generic drugs from being approved for marketing if the patent-holding company alleges the generic drug would infringe its patent. The US and Canada already have such systems in place. The Canadian regulations are regularly abused by patented drug companies to obtain automatic injunctions blocking competitors from the marketplace for years based on mere allegations, and have been described by the Supreme Court of Canada as "draconian."[2]

- Data and market exclusivity periods: The TPP will require countries to grant new and longer periods (for some countries) of "data exclusivity" over information about a drug's safety and efficacy that is submitted to drug regulators in order to get approval to sell the drug. By blocking the use of this information to assess the quality of subsequent, generic versions of that drug, data exclusivity rules are another way, separate from the patent status of a drug, to delay the entry of generic competitors into the market and thereby maintain a monopoly in the market. Related to this, and particularly noteworthy in the TPP, are the controversial new rules on biologic medicines – i.e., those made from biological sources or processes (as opposed to being chemically synthesized like conventional drugs), such as vaccines, blood products and gene therapies. The category of biologics includes new treatments for cancer and various immune conditions, and includes some of the most expensive pharmaceuticals on the market. The TPP would require countries to give 8 years of "effective market protection" (i.e., monopoly) to makers of biologic drugs, whether through the application of data exclusivity rules, or these rules in combination with undefined "other measures," before any more affordable, follow-on "biosimilar" drugs (akin to generic versions of conventional drugs) could be allowed to compete in the market.

- New, harsher enforcement: TPP countries must ensure they provide for civil, administrative and criminal procedures for the enforcement of drug companies' intellectual property rights. This includes powers for customs officers to detain shipments, including of items in transit to other countries simply based on a "suspicion" of trademark infringement – provisions that have already previously been abused in Europe to interfere with the shipment of legitimate generic medicines between developing countries. It also would allow courts to damages for an infringement based on the "suggested retail price" – i.e., the price suggested by the patented drug company, with an obvious consequence of inflating damages.

These provisions in the TPP's intellectual property chapter will delay, impede or chill competition in the marketplace, which is a critical factor in bringing down the prices of medicines – as has been shown vividly by the global experience with antiretroviral drugs needed to treat millions of people with HIV.[3] Such delays come at the expense of millions of people who cannot afford medicines when pharmaceutical companies can use their monopolies to charge high prices.

[2] *Merck Frosst v. Canada (Minister of National Health and Welfare)*, [1998] 2 SCR 193.
[3] B. Waning et al., "A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries," *Journal of the International AIDS Society* 2010; 13: 35, online: www.jiasociety.org/index.php/jias/article/view/17573.

2. Challenging drug formulary prices, weakening controls on drug company marketing

A second area of concern is the so-called annex on "transparency and procedural fairness for pharmaceutical products and medical devices." Its ambiguous wording could create new opportunities for pharmaceutical companies to challenge and undermine decisions on how drugs get listed for reimbursement, and at what prices, in relation to "national health care programmes" operated by "national health authorities." (In the Canadian context, any such provisions for challenging reimbursement decisions would create yet another complication in eventually introducing a truly national pharmacare program, something that has long been recommended for Canada by various experts and commissions so as to fill a disturbing gap in the country's health care system.)

In addition, this annex in the TPP could further undermine efforts to properly regulate in the public interest the activities of drug companies in marketing of their products, including regulating direct-to-consumer advertising. Such regulation is already weak in Canada, and largely non-existent in the United States. The TPP would compel countries to allow drug companies to disseminate information online directly to health professionals and to consumers, despite ample evidence suggesting that, while such practices contribute significantly to the profit margins of pharmaceutical companies, there is little or no benefit to patients and indeed some risk of harm.[4]

3. Expanded rules for corporations to sue governments for regulating in the public interest

Finally, the TPP includes a chapter on "investment" that would give pharmaceutical companies rights to sue sovereign governments over "interference" with their "expectations" of future profit or merely reduce their (expected) value of their investment – including through various regulations aimed at protecting public interests.

Such chapters, setting up "investor-state dispute settlement" procedures, have become a standard feature of many trade agreements, leading to hundreds of claims by corporations challenging a wide range of public interest regulations. But until the TPP, they have not generally extended to define "investment" as including intellectual property rights—now, under the TPP, they are explicitly included. This opens up a whole new route for pharmaceutical companies to try to derail laws or regulations that interfere with their expected profits. In fact, Canada is already facing an unprecedented suit by Eli Lilly under this sort of chapter in an existing trade agreement (NAFTA), which only highlights the dangers of including yet more such measures in the TPP.[5]

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[4] E.g., B. Mintzes, *What are the Public Health Implications?: Direct-to-Consumer Advertising of Prescription Drugs in Canada*, Ottawa: Health Council of Canada, January 2006, online: http://healthcouncilcanada.ca/tree/2.38-hcc_dtc-advertising_200601_e_v6.pdf; J. Lexchin & B. Mintzes, "A compromise too far: A review of Canadian cases of direct-to-consumer advertising regulation," *International Journal of Risk & Safety in Medicine* 2014; 26(4): 213-225.

[5] D. Tencer, Eli Lilly's NAFTA Lawsuit Threat Against Canada Prompts Calls For Review Of Investor Rights," *Huffington Post,* 4 September 2013, online: www.huffingtonpost.ca/2013/09/04/eli-lilly-lawsuit-nafta-canada_n_3861869.html. Documents available the website of the Department of Foreign Affairs, Trade and Development: http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng.

Our concerns are widely shared by health and human rights advocates around the world.

As outlined above, the TPP text pushes beyond the rules of the WTO TRIPS Agreement – which rules are already proving challenging for many developing countries – with the effect of further limiting the room for manoeuvre that countries need in order to protect the public good, including by trying to achieve equitable, universal access to medicines. UN agencies have repeatedly expressed concern over provisions in trade agreements limiting access to affordable medicines (particularly in developing countries).[6] The UNAIDS Executive Director called on the TPP negotiating countries to refrain from including such "TRIPS-plus" provisions in the agreement.[7] So, too, have ten UN Special Rapporteurs on various human rights issues: in a joint statement they expressed concern over the impact of more stringent intellectual property rules and "investor-state dispute settlement" provisions allowing corporations to sue states for laws and regulations aimed at protecting the public interest. They specifically expressed concern about the TPP (and another major trade agreement under negotiation, the Transatlantic Trade and Investment Partnership, TTIP), and they called on states to revisit these treaties to ensure they do not undermine human rights and to ensure an assessment of the treaties' impact on human rights, both before and after they come into effect.[8]

In fact, it is precisely the experience so far with the existing international rules on intellectual property, and the grave concern raised by the rules becoming even more restrictive for access to medicines through other international "free trade" agreements, that led the high-level Global Commission on HIV and the Law to take up this issue, among others, in its ground-breaking report a few years ago. The Global Commission included former presidents and judges, and other leading experts on HIV, law and/or human rights, and it received hundreds of submissions and heard testimony in regional dialogues held around the world. In their final report, the Commissioners called for an immediate global moratorium on including any new provisions on intellectual property in any international treaty that would further restrict the policy options available to countries to improve access to medicines at affordable prices.[9]

The United States, Mexico and Canada should heed these cautions and recommendations. In its potential impact on access to affordable medicines, domestically and globally, the TPP flies in the face of what is needed to respond to major public health challenge raised by both communicable diseases (including HIV, tuberculosis, malaria and others) and non-communicable diseases and health conditions (which represent an even greater, and growing, burden on the populations, health systems and economies of many countries, including developing countries). Instead of accepting the provisions of the TPP as they stand, our three countries should instead demonstrate international leadership in global health and honour its repeated commitments to global health, including access to medicines.

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[6] UNDP & UNAIDS, *Issue Brief: The Potential Impact of Free Trade Agreements on Public Health* (2012), online: http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf.

[7] UNAIDS, *Press statement: UNAIDS calls on trade negotiators to uphold governments' commitments to public health and access to medicines*, 28 July 2015, online: http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2015/july/20150728_trips_plus.

[8] Office of the UN High Commissioner for Human Rights, News release: "UN experts voice concern over adverse impact of free trade and investment agreements on human rights," Geneva, 2 June 2015, online: www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16031.

[9] Global Commission on HIV and the Law, *Risks, Rights & Health* (New York: UNDP, 2012), Chapter 6 (pp. 76-87), online: http://www.hivlawcommission.org/.

President Obama, President Peña Nieto and Prime Minister Trudeau, when you meet in Ottawa on the occasion of the trilateral North American Leaders' Summit, we urge you to:

- Commit to a full, transparent, independent assessment of the TPP's impact on human rights, including access to medicines;

- Refrain from ratifying the TPP as long as it contains any "TRIPS-plus" provisions that exceed the already-restrictive rules on intellectual property that have been adopted at the WTO; and

- Refrain from ratifying any deal that extends the discredited, damaging "investor-state dispute settlement" system to cover intellectual property or other laws and regulations affecting pharmaceuticals, as this would enable pharmaceutical companies to impede regulation of this sector in the public interest.

Antiretroviral drugs have a crucial role to play in saving millions of people from dying of AIDS, and in preventing millions of new HIV infections – thereby moving the world toward the Sustainable Development Goal of ending the AIDS epidemic as a public health threat by 2030. And, of course, the urgency of the need for affordable medicines extends far beyond the AIDS epidemic to encompass other communicable and non-communicable diseases. But the goal of achieving universal access to such medicines will never be achievable as long as governments continue negotiating new trade agreements that keep raising barriers and keep life-saving medicines priced out of reach.

Sincerely, the undersigned:

Canadian HIV/AIDS Legal Network
Grandmothers Advocacy Network
CATIE
Canadian Treatment Action Council
Global Fund Advocates Network
Interagency Coalition on AIDS and Development
Canadian Working Group on HIV and Rehabilitation
Canadian Aboriginal AIDS Network
Canadian Association of Nurses in AIDS Care