



## **Towards a New NAFTA: Safeguarding Public Health and Access to Medicines**

Submission to Global Affairs Canada:  
Consultations on the renegotiation and modernization of the  
North American Free Trade Agreement

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**Canadian HIV/AIDS Legal Network**  
1240 Bay Street, Suite 600  
Toronto, Ontario  
Canada M5R 2A7

Telephone: +1 416 595-1666  
Fax: +1 416 595-0094

[www.aidslaw.ca](http://www.aidslaw.ca)

**The Canadian HIV/AIDS Legal Network promotes the human rights of people living with, at risk of or affected by HIV or AIDS, in Canada and internationally, through research and analysis, litigation and other advocacy, public education and community mobilization.**

*Le Réseau juridique canadien VIH/sida fait valoir les droits humains des personnes vivant avec le VIH ou le sida et de celles qui sont à risque ou affectées autrement, au Canada et dans le monde, à l'aide de recherches et d'analyses, d'actions en contentieux et d'autres formes de plaidoyer, d'éducation du public et de mobilisation communautaire.*

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# INTRODUCTION

The Canadian HIV/AIDS Legal Network (the “Legal Network”) welcomes this opportunity to provide submissions to Global Affairs Canada on the scope of the renegotiation and modernization of the existing North American Free Trade Agreement (NAFTA).

Given the potential impact, domestically and globally, of a new trade agreement between Canada, the United States and Mexico, this briefing focusses on how respect for human rights, including safeguarding public health and ensuring equitable access to affordable medicines, has a crucial role to play in saving millions of people from dying of AIDS and preventing millions of new HIV infections. This public health imperative is reflected in the global Sustainable Development Goals agreed by all countries, including Canada, at the United Nations.

The Legal Network works for the human rights of people living with HIV and of communities particularly affected by HIV, both in Canada and internationally. We are also a founding member of the Global Treatment Access Group (GTAG), a working group bringing together Canadian organizations advocating for greater access to medicines, and other aspects of the human right to the highest attainable standard of health, in developing countries.

Foreign Affairs Minister Chrystia Freeland has declared that modernization is the goal of the forthcoming NAFTA renegotiations. Minister Freeland noted that the renegotiations represent an opportunity to determine how best to “align NAFTA with new realities.”<sup>1</sup> The Canadian government has expressed its desire to ensure that the new NAFTA trade agenda is progressive and “contribute[s] meaningfully to the Government’s overall economic, social, and environmental policy priorities.”<sup>2</sup> In light of these ambitions, the Legal Network aims to provide information on the very real impact that NAFTA has on the protection and promotion of a range of human rights, in Canada and abroad, as the renegotiation moves forward.

Discussions about NAFTA have historically focused on the economies of its member countries. The repercussions arising from the implementation of NAFTA’s provisions, however, affect stakeholders in each member country far beyond economics alone. The agreement’s intellectual property and investor-state dispute resolution provisions, in particular, affect the access to, and affordability of, medications for some of the most vulnerable individuals in these three countries.

Furthermore, history shows that the provisions in NAFTA have implications beyond Canada, the U.S. and Mexico. Provisions on intellectual property first negotiated in the

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<sup>1</sup> Government of Canada, *Statement by Foreign Affairs Minister on NAFTA*, May 18, 2017. Available at [www.canada.ca/en/global-affairs/news/2017/05/statement\\_by\\_foreignaffairsministeronnafta.html](http://www.canada.ca/en/global-affairs/news/2017/05/statement_by_foreignaffairsministeronnafta.html).

<sup>2</sup> Government of Canada, “Ministerial Instructions Amending the Ministerial Instructions Respecting the Express Entry System, 2017-1,” *Canada Gazette: Government Notices* 151,22 (June 3, 2017). Available at [www.gazette.gc.ca/rp-pr/p1/2017/2017-06-03/html/notice-avis-eng.php](http://www.gazette.gc.ca/rp-pr/p1/2017/2017-06-03/html/notice-avis-eng.php).

Canada-U.S. Free Trade Agreement (in 1988), at the urging of the patented pharmaceutical industry, were then replicated and even tightened in NAFTA's intellectual property chapter (in 1993), reflecting a particular model of intellectual property privileges agreed among three countries (two high-income and one middle-income) belonging to the Organization for Economic Cooperation and Development (OECD). However, these provisions on intellectual property were then further replicated, almost verbatim, in the WTO's *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) in 1994, thereby extending that model to the vast majority of the world's countries, despite vastly different levels of industrial development, income levels (including degrees of income inequality), disease burden and strength of health systems. The effects of this model have been felt for nearly 25 years, and are still being felt, not least as the HIV epidemic ravages many countries needing rapid, sustainable access to affordable medicines.

Given the clear lesson of history, it would be a mistake to think that what is agreed in a renegotiated NAFTA will only affect the three countries that are directly parties to the agreement. The human rights and public health imperatives of equitable access to affordable medicines are certainly at stake for those in Canada, the U.S. and Mexico. They are also at stake, however, for hundreds of millions of people in other countries: should NAFTA provisions further constrain governments' "policy space" for protecting and advancing the public interest in access to affordable medicines, governments in other countries will eventually face pressure — in particular from the U.S. government and the patented pharmaceutical industry — to adopt similar provisions in subsequent trade agreements. Conversely, should the NAFTA parties agree to strengthen public interest protections in a renegotiated agreement, as we urge here, this would set a positive precedent that is useful elsewhere to defend against ongoing demands from the pharmaceutical industry and the U.S. for ever-more stringent rules that generate more profits for the already highly profitable pharmaceutical industry but impede or delay access to medicines for substantial numbers of those in need.

The Legal Network is particularly concerned about two main areas that will determine the impact of the new NAFTA on access to medicines, and therefore on public health and human rights:

- (i) the rules on intellectual property; and
- (ii) the rules setting out how corporations resolve disputes with governments ("investor-state dispute settlement").

How intellectual property rules can either improve, or undermine, the ability of some of the world's poorest to obtain lower-cost medicines has been repeatedly and well-documented. Canadians already pay some of the highest drug prices in the world and spending on pharmaceutical products is one of the three largest elements of our overall

health-care spending, year after year.<sup>3</sup> Meanwhile, in the absence of a national, universal pharmacare plan, available evidence indicates that a significant percentage of Canadians experience the cost of medication as a barrier to proper health care. A renegotiated NAFTA must support, and not further complicate, the already challenging task of developing universal, equitable pharmacare coverage across the country.<sup>4</sup>

Canada should also commit to ending the tragic global gap in access to medicines, particularly burdensome for developing countries facing multiple major public health challenges — including, but not limited to, HIV.<sup>5</sup> Given the broader global implications of the provisions of a renegotiated NAFTA, Canada must demonstrate this commitment in rejecting any intellectual property rules more stringent than those already embedded in the current NAFTA, and in fact should use the opportunity of the renegotiation to advance a more health-friendly approach to such provisions in an international trade agreement.

Of equal concern are investor-state dispute settlement (“ISDS”) clauses in international trade deals, such as those which exist in both NAFTA and the currently unratified Trans-Pacific Partnership Agreement (“TPP”). Until now, ISDS provisions in trade agreements have not generally extended to defining “investment” as including intellectual property claims. This scope was, and is, the case under NAFTA as originally negotiated. However, under the terms agreed in the TPP, these claims are explicitly included. This fact presents a new route for pharmaceutical companies to try to derail laws or regulations that interfere with their expected profits. In the recently settled Eli Lilly lawsuit against Canada under NAFTA, the multinational pharmaceutical company sought to advance an unprecedented interpretation of NAFTA that would have extended the application of its investor-state dispute settlement mechanism to enforce its intellectual property claims. While fortunately unsuccessful, Eli Lilly’s case highlights the dangers of including yet more such measures in a new trade agreement — particularly with the explicit extension of ISDS provisions to include intellectual property claims.

If problematic intellectual property rules, coupled with insidious dispute resolution regimes such as the one included in the existing NAFTA, were to make their way into a new North American trade deal, hundreds of millions of vulnerable people could face

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<sup>3</sup> Canadian Institute for Health Information, *National Health Expenditure Trends, 1975 to 2015* (Ottawa: CIHI, 2015). Available at [www.cihi.ca/en/spending-and-health-workforce/spending/national-health-expenditure-trends](http://www.cihi.ca/en/spending-and-health-workforce/spending/national-health-expenditure-trends).

<sup>4</sup> M. Dutt, *Affordable Access to Medicines: A Prescription for Canada* (Ottawa: Canadian Doctors for Medicare and Canadian Centre for Policy Alternatives, 2014). Available at [www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2014/12/Affordable\\_Access\\_to\\_Medicines.pdf](http://www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2014/12/Affordable_Access_to_Medicines.pdf).

<sup>5</sup> This commitment was reflected in the widespread support — including from 80% of Canadians polled — for legislative proposals in front of the last Parliament (e.g., Bill C-398) that were aimed at fixing the flaws in Canada’s Access to Medicines Regime. Such fixes remain needed if the regime is ever to deliver on Parliament’s previous unanimous pledge (more than a decade ago) to support developing countries in getting more affordable, generic medicines — rather than remaining moribund, with only one licence issued under the system, authorizing a limited quantity of just one medicine (for treating HIV) to one country (Rwanda). See Canadian HIV/AIDS Legal Network, *Fixing Canada’s Access to Medicines Regime (CAMR): 20 Questions & Answers*, 2012. Available at [www.aidslaw.ca/site/fixing-canadas-access-to-medicines-regime-camr-20-questions-answers](http://www.aidslaw.ca/site/fixing-canadas-access-to-medicines-regime-camr-20-questions-answers).

even higher drug costs. Delaying the entry of lower-cost generics into the market would devastate efforts to make medicines available to as many people as possible. Access to generic antiretroviral drugs, in particular, has been and remains critical to saving millions of people from dying of AIDS, and preventing millions of new HIV infections, around the world. It would be irresponsible and immoral to negotiate a new NAFTA that would not only be detrimental to the health of Canadian residents but also contribute to ongoing global health inequity.

## INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES

According to the World Health Organization and the World Bank, 400 million people worldwide lack healthcare, including access to medicines that have saved and extended the lives of people in richer, developed countries.<sup>6</sup> With 36.7 million people living with HIV/AIDS, and 1.1 million people having died from AIDS-related illnesses in 2015 alone, the global epidemic continues to devastate entire countries and regions.<sup>7</sup> Similarly, tuberculosis and malaria result in deaths mainly among the poorest and most vulnerable of the global population, given their extremely limited access to effective forms of treatment.

The latest UNAIDS data shows that the international community has made substantial progress in scaling up access to life-saving HIV medicines, such that, in the last two years, the number of people living with HIV on antiretroviral therapy has increased by about a third, reaching 17 million people.<sup>8</sup>

Due primarily to generic competition, made possible by some hard-won flexibility in WTO rules and in the domestic legislation of some key countries, the price of ARVs has dropped by more than 99% over the last decade, which has made this public health success possible. However, less than half of the estimated 36.7 million people living with HIV have access to treatment that is clinically indicated. The price of newer drugs is prohibitive to the wide-scale implementation of national treatment programmes,<sup>9</sup> making it essential to preserve and enhance the flexibility available in intellectual property rules for countries to protect the public interest, including the promotion of equitable access to medicines.

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<sup>6</sup> World Health Organization and World Bank, *Tracking Universal Health Care Coverage: First Global Monitoring Report*, 2015. Available at [http://apps.who.int/iris/bitstream/10665/174536/1/9789241564977\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/174536/1/9789241564977_eng.pdf?ua=1).

<sup>7</sup> UNAIDS, *Fact Sheet*, November 2016. Available at [www.unaids.org/sites/default/files/media\\_asset/UNAIDS\\_FactSheet\\_en.pdf](http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf).

<sup>8</sup> UNAIDS, *Global AIDS Update*, 2016. Available at [www.unaids.org/sites/default/files/media\\_asset/global-AIDS-update-2016\\_en.pdf](http://www.unaids.org/sites/default/files/media_asset/global-AIDS-update-2016_en.pdf).

<sup>9</sup> Médecines Sans Frontières (MSF), *Untangling the Web of Antiretroviral Price Reductions*, 18th edition, July 2016. Available at [www.msfacecess.org/content/report-untangling-web-antiretroviral-price-reductions-18th-ed-july-2016](http://www.msfacecess.org/content/report-untangling-web-antiretroviral-price-reductions-18th-ed-july-2016).

These high prices of many new medicines pose an enormous challenge to public health care systems or patients who have to pay for them out of pocket, as is the situation in most low- and middle-income countries. Many countries are unable to benefit from lower priced generics due to delays with market entry or lack of effective competition. Restrictive rules on intellectual property in relation to pharmaceuticals, in particular, can prevent companies from manufacturing less expensive copies of brand-name drugs, interfering with the distribution of life-saving medicines to millions of the world's poor.

Pharmaceutical companies argue that patents are crucial for innovation and that without them there will be no financial incentive to fund the costs of discovery and development of new medicines. In practice, however, the research and development (R&D) costs shouldered by such companies is far less substantial than the sums those companies spend on sales and marketing.<sup>10</sup> Many of the most important research gains in medicines have been funded directly or indirectly by governments, not private companies.<sup>11</sup>

In addition, the prices of medicines in developing countries are often well above production costs. Developing countries account for a small fraction of the global pharmaceutical market and the generation of income to fund more research and development is not dependent on profit from these markets. The patent system has also not provided sufficient incentive for R&D of new medicines needed for diseases that afflict public health, including neglected diseases and “orphan” drugs, because forecasts deem the market too small or commercially unattractive.<sup>12</sup>

It is 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 address this issue in a 2012 report. The Global Commission included former presidents and judges, and other leading experts on HIV, law and human rights, and it received hundreds of submissions and heard testimony in regional dialogues held around the world. In its final report, the Commission 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.<sup>13</sup>

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<sup>10</sup> D. Light and R. Warburton, “Demythologizing the high costs of pharmaceutical research,” *BioSocieties* (2011): pp. 1–17; R. Anderson, “Pharmaceutical industry gets high on fat profits,” *BBC News*, November 6, 2014. Available at [www.bbc.com/news/business-28212223](http://www.bbc.com/news/business-28212223).

<sup>11</sup> B. Sampat and F. Lichtenberg, “What are the respective roles of the public and private sectors in pharmaceutical innovation?” *Health Affairs* 30/2 (2011): pp. 332–339.

<sup>12</sup> World Health Organization, “Intellectual property protection: impact on public health,” *WHO Drug Information* 19,3 (2005): pp. 236–241. Available at [www.who.int/medicines/areas/policy/AccessstoMedicinesIPP.pdf](http://www.who.int/medicines/areas/policy/AccessstoMedicinesIPP.pdf).

<sup>13</sup> “Chapter 6: Medicines for Whom? Intellectual Property Law and the Global Fight for Treatment,” in UNDP Global Commission on HIV and the Law, *HIV and the Law: Risks, Rights & Health*, July 2012, pp. 76–87. Available at [www.hivlawcommission.org/report](http://www.hivlawcommission.org/report).

Most recently, similar concerns have been expressed in the report of the UN Secretary-General's High-Level Panel on Access to Medicines.<sup>14</sup> Co-chaired by the former presidents of Switzerland and Botswana, with representation from eminent experts from various fields, the Panel was established out of concern that international and domestic rules on patents and other aspects of intellectual property — including more restrictive rules being negotiated in successive international trade agreements — are fuelling an ongoing public health and human rights crisis, particularly in low- and middle-income countries, and increasingly posing unsustainable burdens on high-income countries as well. The Panel was asked by the UN Secretary-General to recommend remedies for the “incoherence” between human rights and public health on the one hand, and on the other hand, rules on intellectual property (e.g., those further extending drug companies’ patent and data monopolies).

Among other findings and recommendations, the High-Level Panel has called on countries to make full use of any “flexibilities” under international agreements such as the WTO’s TRIPS Agreement, as part of fulfilling their human rights obligations to ensure access to medicines.<sup>15</sup> Underscoring the importance of preserving what flexibilities exist under TRIPS to promote equitable access to affordable medicines, the High-Level Panel outlines its concern with pressure on countries to not use those flexibilities.

The High-Level Panel also emphasized its concern with “the proliferation of free trade agreements containing expansive patent and test data protections on health technologies” that exceed the requirements of TRIPS Agreement. In the Panel’s view, such agreements endanger countries’ efforts to ensure access to medicines and other health technologies and run counter to their human rights obligations. The Panel notes that countries concluding such agreements are in dereliction of their human rights obligations by doing so before undertaking a transparent, public assessment of its impact on access to medicines and public health. While civil society organizations and academic researchers have prepared some such analyses, Canada does not appear to have undertaken any similar assessment to date (e.g., in relation to the TPP).

Canada can and should honour its repeated commitments to global health, including access to medicines, by implementing the recommendations of the High-Level Panel as

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<sup>14</sup> UN, *The United Nations Secretary-General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies*, September 2016. Available at [www.unsgaccessmeds.org/final-report](http://www.unsgaccessmeds.org/final-report). The High-Level Panel’s report was released shortly before Canada hosted in Montréal last year the 5th Replenishment Conference for the Global Fund to Fight AIDS, Tuberculosis and Malaria — the largest, most important multilateral body funding the global response to these three pandemics. Canada is a major donor to the Global Fund; however the funds it contributes, including for the purchase of life-saving medicines and other pharmaceutical products, are squandered unnecessarily to the extent that intellectual property policies, including those negotiated via trade agreements such as the TPP, restrict countries’ ability to use those funds as cost-effectively as possible by purchasing lower-priced, generic medicines and products as much as possible.

<sup>15</sup> This includes a specific recommendation to apply stricter standards for granting patents on pharmaceutical products in the first place, and to adopt laws that facilitate quick implementation of compulsory licences on patented products to address public health needs — including compulsory licencing in order to export supplies of lower-cost, generic medicines to other countries (as was supposed to be the case with the deficient CAMR).

it modernizes and renegotiates NAFTA. In particular, the government should resist the inevitable efforts that pharmaceutical corporations will make to strengthen and prolong the private monopoly rights they already enjoy, which could impede and delay the competition that brings medicine prices down. Canada should refuse to ratify any trade deal that would 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.<sup>16</sup>

## **RULES ALLOWING CORPORATIONS TO SUE GOVERNMENTS REGULATING IN THE PUBLIC INTEREST**

In practice, the ISDS clause within Chapter 11 of NAFTA allows businesses to sue member countries for significant sums of money for laws and policies that may have been adopted to safeguard human rights or the environment, but have in some way limited free trade possibilities.<sup>17</sup> The language agreed to in the TPP goes even further, referring to interference with “expectations of profit.” The inclusion of an ISDS clause in international trade agreements can create a significant chilling effect, as it effectively sets out a mechanism whereby member countries can be penalized for adopting regulations in the public interest, such as to protect access to generic and essential medicines, food security, or the environment; to raise the minimum wage; or to address discrimination against marginalized groups. The renegotiation and modernization of NAFTA is an opportunity to ensure that no such clause is included in the new deal.

ISDS 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. They have been among the features provoking the strongest opposition to such deals, including most recently the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union, as well as the TPP. Such provisions are not primarily aimed at removing at-the-border barriers to trade, but instead at disciplining governments for domestic regulatory measures aimed at protecting various legitimate public interests.

Out of the three countries that are parties to NAFTA, Canada has been sued the most. Over 70 percent of the claims that have been made under NAFTA since 2005 have

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<sup>16</sup> 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* 13 (2010): p. 35. Available at [www.jiasociety.org/index.php/jias/article/view/17573](http://www.jiasociety.org/index.php/jias/article/view/17573).

<sup>17</sup> Government of Canada, *Text of the North American Free Trade Agreement (NAFTA)*. Available at [www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/nafta-alena/text-texte/11.aspx?lang=eng](http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/nafta-alena/text-texte/11.aspx?lang=eng).

been brought against Canada.<sup>18</sup> In fact, Canada recently faced an unprecedented lawsuit by Eli Lilly and Company (“Eli Lilly”) under the ISDS clause in NAFTA, highlighting the dangers of including yet more such measures in a modernized agreement.<sup>19</sup>

In September 2013, Eli Lilly, an American pharmaceutical company, launched a lawsuit against Canada after both the Federal Court (Trial Division) and Federal Court of Appeal, applying long-settled requirements in Canadian patent law for obtaining a valid patent, set aside the patents on two drugs patented by Eli Lilly on the basis that they had failed to satisfy these requirements. Seeking to use the NAFTA tribunal system to force a change to these long-standing principles of Canadian patent law, Eli Lilly launched a proceeding against Canada, claiming \$500 million in damages under NAFTA’s investment clause.<sup>20</sup> Eli Lilly’s arguments rested on arguments that would have extended NAFTA’s “investor protection” chapter (Chapter 11) to cover intellectual property claims (under Chapter 17), despite such claims not being explicitly stipulated in the deal. Prior to this case, no pharmaceutical company had ever filed an investor-state challenge based on intellectual property rights.

Under the logic of Eli Lilly’s claim, pharmaceutical companies should enjoy unlimited protections from any new laws enacted by a government that affect foreign investors’ profits. The lawsuit could very well have paved the way for foreign intellectual property investors to directly sue virtually any government — rich or poor — to enforce companies’ interpretations of treaty provisions related to intellectual property. Such claims could effectively punish governments from adopting regulations in the public interest, or create a chilling effect and deter them from doing so to begin with. Even under the treaties that make up the WTO system, disputes about compliance with treaty obligations can only be brought by one member country against another. This is why multinational corporations seek ISDS clauses, and broad wording in them, via other trade agreements — such as the TPP or via a renegotiation of NAFTA: it gives them another avenue to directly try to force sovereign governments to remove laws, regulations or policies that interfere with their “expectations of profit.”

Fortunately, the NAFTA tribunal rejected the substance of Eli Lilly’s claim in March 2017. Had the tribunal accepted Eli Lilly’s interpretation of the law, it would have radically altered the direction of Canadian patent law by tilting the balance between

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<sup>18</sup> Canadian Centre for Policy Alternatives, *NAFTA Chapter 11 Investor-State Disputes to January 1, 2015*. Available at [www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2015/01/NAFTA\\_Chapter11\\_Investor\\_State\\_Disputes\\_2015.pdf](http://www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2015/01/NAFTA_Chapter11_Investor_State_Disputes_2015.pdf).

<sup>19</sup> D. Tencer, “Eli Lilly’s NAFTA Lawsuit Threat Against Canada Prompts Calls For Review Of Investor Rights,” *Huffington Post*, September 4, 2013. Available at [www.huffingtonpost.ca/2013/09/04/eli-lilly-lawsuit-nafta-canada\\_n\\_3861869.html](http://www.huffingtonpost.ca/2013/09/04/eli-lilly-lawsuit-nafta-canada_n_3861869.html). See also the documents available at the website of the Department of Foreign Affairs, Trade and Development. Available at [www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng](http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng).

<sup>20</sup> *Eli Lilly and Co. v. Government of Canada*, Case No. UNCT/14/2, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven (Strattera and Zyprexa) (ICSID 2013). Available at [www.italaw.com/sites/default/files/case-documents/italaw1530.pdf](http://www.italaw.com/sites/default/files/case-documents/italaw1530.pdf).

patent protection and access to generic medicine heavily toward increased patent protection for patent-holding pharmaceutical companies. The potential legislative or jurisprudential changes that would have followed a NAFTA tribunal finding in favour of Eli Lilly would have created immense uncertainty for generic pharmaceutical manufacturers whose business revolves around assessing and, where appropriate, challenging the validity of patents on pharmaceutical products. This would prevent generic pharmaceutical companies from competing, and allows the brand-name pharmaceutical industry to use its monopoly to keep prices artificially high.

ISDS has received overwhelming criticism and has been firmly discredited over the past several years.<sup>21</sup> Many studies have shown that investment treaties have no effect on governments' ability to attract foreign direct investment ("FDI"), with some even finding a negative impact on FDI. Qualitative research suggests that such treaties are not a decisive factor in whether investors invest abroad.<sup>22</sup>

In contrast, a truly modernized NAFTA would support and protect human rights and public health, as well provide as secure policy space for the governments of Canada, the United States and Mexico to advance the economies and societies of these three countries without facing prohibitively costly obligations and liability risks.

## CONCLUSIONS AND RECOMMENDATIONS

Medicines have a crucial role to play in not only saving millions of people from dying of AIDS, but also preventing millions of new HIV infections and moving the world toward the goal of ending the epidemic, as has been agreed by all countries in Sustainable Development Goal 3.<sup>23</sup> This goal, however, will never be achievable as long as governments — including Canada's — continue negotiating new trade agreements that keep raising barriers to the realization of universal access to such medicines.

While the increased employment and prosperity that flows from growing trade and investment — which is not automatically a given outcome of a trade agreement, nor necessarily a substantial net gain where there may be some — can boost the

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<sup>21</sup> A. Beattie, "Investment treaties: EMs have a rethink," *The Financial Times*, October 16, 2014; "The arbitration game," *The Economist*, October 11, 2014. Available at [www.economist.com/news/finance-and-economics/21623756-governments-are-souring-treaties-protect-foreign-investors-arbitration](http://www.economist.com/news/finance-and-economics/21623756-governments-are-souring-treaties-protect-foreign-investors-arbitration); P. Coy, B. Parkin and A. Martin, "In Trade Talks, It's Countries vs. Companies", *Bloomberg*, March 20, 2014. Available at [www.bloomberg.com/news/articles/2014-03-20/in-trade-talks-its-countries-vs-dot-companies](http://www.bloomberg.com/news/articles/2014-03-20/in-trade-talks-its-countries-vs-dot-companies); A. Martin, "Philip Morris Leads Plain Packs Battle in Global Trade Arena," *Bloomberg*, August 22, 2013; A. Martin, "Coup d'Etat to Trade Seen in Billionaire Toxic Lead Fight," *Bloomberg*, May 10, 2013; A. Martin, "Treaty Disputes Roiled by Bias Charges," *Bloomberg*, July 10, 2013.

<sup>22</sup> For an overview of the literature, see Lauge Skovgaard Poulsen, "The Importance of BITs for Foreign Direct Investment and Political Risk Insurance: Revisiting the Evidence" in K. Sauvant, ed., *Yearbook on International Investment Law & Policy 2009–2010* (New York: Oxford University Press, 2010).

<sup>23</sup> UN, "Goal 3: Ensure healthy lives and promote well-being for all at all ages." Available at [www.un.org/sustainabledevelopment/health](http://www.un.org/sustainabledevelopment/health).

enjoyment of human rights, the contrary is true if such initiatives are not managed responsibly. A modernized NAFTA must safeguard countries' ability to manoeuvre in order to protect the public good, including by trying to achieve equitable, universal access to medicines.

The concerns raised in this submission are widely shared by health and human rights advocates around the world, many of whom have spoken out about analogous issues with regard to the TPP. UN agencies have repeatedly expressed concern over provisions in trade agreements limiting access to affordable medicines (particularly in developing countries),<sup>24</sup> and earlier this year, the UNAIDS Executive Director called on the TPP-negotiating countries to refrain from including such "TRIPS-plus" provisions in the agreement.<sup>25</sup> So, too, did 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 called on states to revisit these treaties to ensure they do not undermine human rights. They also recommended an assessment of the treaties' impact on human rights, both before and after they come into effect.<sup>26</sup> The UN Secretary-General's High-Level Panel on Access to Medicines has also expressed concern about a "new generation of bilateral and multilateral trade and investment agreements which include 'TRIPS-plus' provisions that progressively ratchet up intellectual property protection and enforcement."<sup>27</sup>

The Legal Network is asking Canada to ensure that a modernized, renegotiated NAFTA safeguards equitable access to life-saving medicines. In keeping with the recommendations of UN agencies and numerous health and human rights experts, the Legal Network urges the government to do the following:

- **Conduct an independent assessment of the human rights impact (including access to medicines) of any new trade deal, including a modernized NAFTA, and ensure that such an assessment be conducted transparently and made available publicly.**
- **Refuse to ratify any new trade deal that contains "TRIPS-plus" provisions and interferes with access to health technologies.**

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<sup>24</sup> UNDP & UNAIDS, *Issue Brief: The Potential Impact of Free Trade Agreements on Public Health*, 2012. Available at [www.unaids.org/sites/default/files/media\\_asset/JC2349\\_Issue\\_Brief\\_Free-Trade-Agreements\\_en\\_0.pdf](http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf).

<sup>25</sup> UNAIDS, *Press statement: UNAIDS calls on trade negotiators to uphold governments' commitments to public health and access to medicines*, July 28, 2015. Available at [www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2015/july/20150728\\_trips\\_plus](http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2015/july/20150728_trips_plus).

<sup>26</sup> Office of the UN High Commissioner for Human Rights, "UN experts voice concern over adverse impact of free trade and investment agreements on human rights," news release, June 2, 2015. Available at [www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16031](http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16031).

<sup>27</sup> *The United Nations Secretary-General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies*.

- **Adopt and apply rigorous definitions of invention and patentability that are in the best interests of the public health of the country and its inhabitants, including by adopting provisions that curtail the evergreening of patents and awarding patents only when genuine innovation has occurred.**
- **Facilitate the issuance of compulsory licences for legitimate public health needs, particularly with regard to essential medicines, pursuant to the 2001 Doha Declaration adopted by WTO Members. In this regard, reform and streamline Canada's Access to Medicines Regime, and support the revision and replacement of the failed mechanism for compulsory licencing for export that was agreed on August 30, 2003, at the WTO.**
- **Commit to investing in adequate research and development (R&D) in response to public health needs, including for diseases for which the market does not currently provide sufficient financial return. Incorporate a binding treaty obligation in a revised NAFTA that would require Canada, the U.S. and Mexico to each contribute to such health R&D in proportion to their respective per capita gross national incomes.**
- **Ensure that universities and research institutions that receive public funding prioritize public health objectives over financial returns in their patenting and licencing practices, and require that knowledge generated by such research be made freely and widely available. Incorporate such a requirement into a new chapter on intellectual property in a revised NAFTA.**
- **Excise the discredited, damaging investor-state dispute settlement system for addressing disputes between governments from NAFTA in its entirety.**