The possible effects of the Trans-Pacific Partnership on the cost and regulation of medicine in Canada

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Summary

Negotiations on the Trans-Pacific Partnership Trade Agreement (TPP) concluded in October of 2015 and the 12 participating TPP countries, including Canada, signed the deal in February of 2016.[1] Though the impact of the TPP on trade flows (imports and exports of goods and services) will be minimal, the deal would place many new constraints on government policy in areas not strictly related to trade.[2]

One of these areas is how governments regulate the pharmaceutical sector and set prices for medicines—two issues of importance mainly for U.S. and Japanese brand-name drug companies. The changes proposed in the TPP will have costs for public and private purchasers of pharmaceutical products including medicines. In particular, the agreement will restrict future policy options in these areas in ways that benefit brand-name producers over consumers and the broader public interest.

This brief examines the possible effects of the TPP on how Canada regulates medicines and how much the country spends paying for them. Among the 30 chapters in the TPP, five contain language specifically related to medicines in the following respects:

1. The chapter on Technical Barriers to Trade (Chapter 8) contains clauses on transparency, regulatory harmonization, and acceptable marketing approval processes that further entrench the views of foreign governments—and by proxy their pharmaceutical sectors—in federal medicines policy with no guarantee that harmonization will be upward (to the highest common denominator) and no additional requirements on Canadian manufacturers to be open about public inspections of their facilities.

2. The chapter on Intellectual Property (Chapter 18) contains additional monopoly rights for brand-name pharmaceutical companies in the form of extended patent terms, while locking in Canada's costly patent-linkage system and permanently setting long data exclusivity terms on traditional and biologic drugs. Depending on whether the TPP or the very similar Comprehensive Economic and Trade Agreement (CETA) with the Europe Union is ratified first, drug costs are expected to rise by between 5% and 12.9% starting in 2023.

3. An annex of the chapter on Transparency and Anti-Corruption (Chapter 26), related to "transparency and procedural fairness for pharmaceutical products and medical devices," could have negative effects on pharmaceutical costs and regulation in the future. Though there is currently no national drug plan in Canada, should one be established this annex would threaten the ability of the federal government to use cost control measures to keep such a plan affordable.

4. The dispute resolution procedures related to investment (Chapter 9) and other parts of the agreement (Chapter 28) create unnecessary and unforeseeable risks to public policy on medicines. Specifically, an investor–state dispute settlement (ISDS) process would allow investors (e.g., brand-name pharmaceutical corporations) in TPP countries to challenge government measures outside the normal court system in largely unaccountable private tribunals whose decisions are binding. Canada is already facing such a challenge from U.S. drug firm Eli Lilly, which is demanding $500 million in compensation for Canadian court decisions invalidating two of its patents on the grounds the patents made claims for the drugs that could not be demonstrated.

Beyond the text of the TPP, there are additional risks to Canada from how it might be interpreted by the U.S. government and the pharmaceutical industry. The U.S. pharmaceutical industry was not satisfied with the outcome of the TPP negotiations, especially with respect to the provisions on intellectual property rights. For example, where industry had pushed for 12 years of data exclusivity protection for biologics, TPP countries would only agree to a maximum of eight years. As a result, the industry will probably be

very aggressive in pushing for the strictest interpretation of the various provisions of the TPP that relate to medications.

In conclusion, the TPP could have profound effects on the criteria that Canada uses to decide on drug safety and effectiveness, how new drugs are approved (or not) for marketing, post-market surveillance and inspection, the listing of drugs on public formularies, and how individual drugs are priced in the future. Some of these implications are necessarily speculative since they depend on future actions that Canada might take (e.g., with respect to national pharmacare), how the various articles in the TPP are interpreted by dispute panels, and how aggressive the pharmaceutical industry is in pursuing its newfound rights in the deal.

Introduction

The Trans-Pacific Partnership (TPP) is a 12-nation trade agreement that supporters liken to an upgrade and expansion of the North American Free Trade Agreement (NAFTA). While negotiations on the TPP began among four Pacific nations in 2004, it became a largely U.S. project when the Obama administration joined in 2008. Canada and Mexico followed their NAFTA partner to the table four years later, in 2012, largely as a defensive move, since the economic opportunities in the TPP for both countries are small to insignificant.

More significant for Canada will be those new chapters in the TPP that create additional constraints on government policy-making in areas that have very little to do with trade. For example, the TPP contains five chapters that specifically relate to medicines: Technical Barriers to Trade (Chapter 8); Investment (Chapter 9); Intellectual Property (Chapter 18); Transparency and Anti-Corruption (Chapter 26); and Dispute Settlement (Chapter 28).

The objective of this paper is to begin a critical examination of the contents of these chapters with the goal of laying out the possible effects the TPP will have on how Canada regulates medicines and how much money the country spends paying for them. Since it is impossible to predict how any trade agreement will be interpreted or enforced, we are left to draw on our experience with previous trade deals that Canada has entered into, such as NAFTA or CETA, and their impact on medicines policy, in order to speculate on how new language in the pacific deal might further do so.[3]

Technical Barriers to Trade (Chapter 8)

The TPP includes several chapters related to government regulation, including those on Sanitary and Phytosanitary Measures (Chapter 7), Technical Barriers to Trade, or TBT (Chapter 8), and Regulatory Coherence (Chapter 25). These chapters, which build on similar rules in the WTO and many Canadian free trade agreements, are absolute; they do not concern themselves *solely* with discriminatory treatment between foreign and domestic firms or goods. Rather, government action is restricted for *all* based on the belief government regulation should be no more trade restrictive than necessary.

The TPP chapter on TBT includes several articles that pertain to the regulation of medicines and other pharmaceutical products that could be described as WTO-plus. Article 7 on transparency in the main body of this chapter sets forth the following requirement:

> *Each Party shall allow persons of the other Parties to participate in the development of technical regulations, standards and conformity assessment procedures by its central government bodies.*[4]

What this means in practice is that the other TPP countries will have the opportunity to provide comments about Canadian regulatory requirements for drug marketing or post-market monitoring of drug safety and effectiveness. Both Japan and the United States have very powerful pharmaceutical industries that could

end up having an indirect effect on Canadian regulations through the participation of the U.S. and/or Japanese governments.

The U.S. government in particular has a very close relationship with the pharmaceutical industry. At a recent WTO meeting of the Council for Trade-Related Aspects of International Property Rights (TRIPS), U.S. negotiators pushed back against requests from the Least Developed Countries (LDC) group for an indefinite extension to their existing exemption from some TRIPS requirements that would, if enforced, create unsustainable costs for governments.

The deputy U.S. Trade Representative was reported to have said the U.S. government could not accede to the demands from the LDCs because certain stakeholders (presumably including the pharmaceutical industry), already upset the TPP negotiations had not produced the results the industry wanted, would not suffer another U.S. step-down on intellectual property.[5] (The U.S. and the LDC group compromised on a 17-year extension at the end of November.)[6]

In addition to Article 7, Annex 8-C to the TBT chapter applies specifically to pharmaceuticals. The five following articles within this annex could potentially affect Canada:

i) Article 5

> *The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonization, as well as regional initiatives in support of such international initiatives, as appropriate, to improve the alignment of their respective pharmaceutical products regulations and regulatory activities.*

In the past, regulatory harmonization, primarily through the International Conference on Harmonization (ICH), has had positive and negative effects on drug regulation in Canada.[7] Up until late 2015, the ICH was controlled by the U.S., European Union, and Japanese drug regulatory agencies and brand-name industry associations in these countries.

In October of 2015, the ICH changed its name to the International Council for Harmonization and expanded its membership.[8] The effect that the structural changes in the ICH will have on the standards that it recommends is speculative, so it is unknown whether further harmonization will lead to lower or higher regulatory standards in Canada.

ii) Article 7bis

> *Each Party shall make its determination on whether to grant marketing authorization for a specific pharmaceutical product on the basis of:*
>
> *(a) information, including, where appropriate, pre-clinical and clinical data, on safety and efficacy;*
>
> *(b) information on manufacturing quality of the product;*
>
> *(c) labelling information related to safety, efficacy and use of the product; and*
>
> *(d) other matters that may directly affect the health or safety of the user of the product.*
>
> *To this end, no Party shall require sale or related financial data concerning the marketing of the product as part of such a determination. Further, each Party shall endeavour not to require pricing data as part of the determination.*

This article sets out the information that regulatory authorities should consider in making a marketing decision. But depending on how it is interpreted, what is not included may be just as important.

For example, the article does not say anything positive or negative about regulatory authorities adopting a "medical need" clause as one of the requirements for approving new drugs. Norway had such a clause before it joined the European Medicines Agency. To meet the medical need test, new drugs approved in Norway needed to offer an advantage over existing products: they should be better therapeutic alternatives than those already on the market or there should be a clear-cut medical need for any new product.

Between 1981 and 1983, the absence of medical need was cited in 147 of the 233 new drug applications rejected by Norwegian authorities.[9] Medical need does not mean follow-on drugs in the same class will automatically be rejected, since at times a second or third drug in a class is superior to the first. Rather, the fact a drug is superior to a placebo should not necessarily lead to marketing approval as is currently the situation in Canada.

If the four criteria for drug approval laid out in this article of the TBT annex are interpreted as a floor (i.e., additional criteria can be used), then Health Canada would be free to adopt a medical need clause in the future. If, however, the criteria are treated like a restrictive list, the option of adopting a Norway-like needs test—with its positive health and cost-savings potential—will vanish forever as an option for Canada.

iii) Article 8

> *Each Party shall administer any marketing authorization process it maintains for pharmaceutical products in a timely, reasonable, objective, transparent, and impartial manner, and identify and manage any conflicts of interest so as to mitigate any associated risks.*

The impact of this article may depend on which country's standards are used to judge an authorization's timeliness. Article 8(c) does make allowances for the "available resources and technical capacity" of the parties. In that regard, the TPP may not require that Canada review drugs as quickly as the U.S. Food and Drug Administration, with its superior resources. (The median approval time in the U.S. is 304 days compared to 350 days in Canada.)[10]

However, Canada could be compared to a country of similar size, such as Australia, and vice-versa. Currently, Health Canada reviews drugs slightly faster than its Australian equivalent.[11] Faster regulatory approvals by Health Canada have been shown to lead to a greater chance a product will subsequently acquire a serious safety warning or be withdrawn from the market for safety reasons.[12]

iv) Article 8(c)

> *If a Party requires marketing authorization for a pharmaceutical product, the Party shall ensure that any marketing authorization determinations are subject to an appeal or review process that may be invoked at the request of the applicant seeking market authorization. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorization determination, such as a dispute resolution or review process, or external to the regulatory body.*

This article says the appeals process for manufacturers whose products have been denied marketing authorization could be either internal to the regulatory body or conducted by an outside body. Health Canada currently has an internal appeals process. Should the department at some point in the future chose to use an external body for appeals, it could conceivably involve industry representatives, since this article says nothing about the composition of such a body.

v) Article 12(c)

> *12. The Parties shall seek to improve their collaboration on pharmaceutical inspection, and to that end each Party shall, with respect to the inspection of pharmaceuticals products within the territory of another Party:*
>
> > *(c) notify that Party of its findings as soon as possible following an inspection and, if the findings will be publicly released, no later than a reasonable time before any such release. However, the inspecting Party is not required to notify its findings if it considers that its findings are confidential and should not be disclosed.*

If national governments are to be required to change their pharmaceutical policies to meet new internationalized standards, this article surely represents a missed opportunity for establishing a superior international standard. Instead of necessitating that inspections of manufacturing facilities be made public, the TPP would allow each Party to claim this information is confidential and should therefore not be released. Health Canada has a poor track record when it comes to transparency, and despite recent minor improvements, this article would specifically allow Health Canada to continue its current policy of secrecy.[13]

Investment and Dispute Settlement (Chapters 9 and 28)

Like almost all Canadian free trade agreements, the TPP includes a chapter on investment protection along with a controversial investor–state dispute settlement process (Chapter 9). Under ISDS, foreign investors may sue a party to the treaty in private arbitration for actions taken by federal, provincial, or local governments that are alleged to violate the substantial rights contained in the treaty's investment chapter.

Those rights include protections against discriminatory treatment (e.g., where foreign and national investors are treated differently by a government action) and expropriation without compensation. But the vast majority of ISDS claims involve other vaguely worded clauses on a foreign investor's "minimum standards of treatment," or their "legitimate expectations," which ISDS tribunals have too frequently interpreted in an expansive way that seriously undermines democratic processes and, occasionally, national legal systems.

Disputes under ISDS clauses in treaties like the TPP are heard outside of the judicial system of the country that is being sued; in general these decisions are not subject to appeal. The tribunals that hear these cases are comprised of three private individuals (usually lawyers) from a rather small pool of arbitrators, many of whom also sometimes serve as lawyers for investors making other ISDS charges.[14] As the European Commission has noted, "This situation can give rise to conflicts of interest—real or perceived—and thus concerns that these individuals are not acting with full impartiality when acting as arbitrators."[15]

University of Toronto law professor David Schneiderman is among a growing list of experts on ISDS who claim the conflict is very real, conferring "enormous discretion" over what is and is not a legitimate government measure on "an elite corps" of investment layers. "As the regime's enforcers, investment tribunals have an immense amount of room to manouevre in determining whether governments have run afoul of treaty text," he commented recently.[16]

EU decision-makers are so concerned about the potential for abuse, the European Commission recently proposed replacing all European treaties containing ISDS, including the CETA with Canada, with a more transparent and (they suggest) judicial investment court. The TPP, on the other hand, makes no attempt to reform the flaws of the ISDS system.

For example, TPP negotiators relegated a modest code of conduct for ISDS arbitrators to a side agreement to be finalized by participating countries at some point before the pact goes into effect. According to an

analysis by the U.S. group Public Citizen:

> *Whether such rules will be effective with respect to tribunalists' direct conflicts of interest is an open question…However, even if the Code of Conduct were to stop the outrageous practice of lawyers with direct financial interests in the companies and issues involved being allowed to serve as "judges," the TPP text does not address the bias inherent in the ISDS system and underlying the business model of lawyers engaged in this field: ISDS tribunalists have a structural incentive to concoct fanciful interpretations of foreign investors' rights and order compensation to increase the number of investors interested in launching new cases and enhance the likelihood of being selected for future tribunals.*[17]

The vagueness of enforceable investment rules in the TPP combined with this extraordinary discretion vested in arbitrators creates potential problems for regulation in any number of policy areas, including related to pharmaceuticals and efforts to control drug costs.

The U.S. pharmaceutical company Eli Lilly is already using the ISDS provisions in NAFTA to sue Canada for $500 million, claiming the decision of the Canadian courts to overturn patents on two Lilly products on the grounds that the patents made claims about the drugs that could not be substantiated, amounts to expropriation without compensation and violates its minimum standards of treatment as protected in the treaty.[18] For any domestic investor or firm in Canada, the ruling of a superior court would be the final say. The investment chapters in treaties like NAFTA and the TPP give multinational firms the ability to sidestep the law.

The TPP investment text does little to curb claims such as Eli Lilly's and may, in fact, make matters worse. Procedurally, the TPP would extend ISDS to investors from all TPP countries, including Japan, which is home to a large pharmaceutical industry. Substantively, and unlike NAFTA, the TPP's investment chapter explicitly covers intellectual property rights in its definition of investment and contains no general exception for matters related to public health.

Problematically, the TPP investment chapter also cross-references and incorporates (e.g., in Article 9.7.5) rights contained in the WTO TRIPS Agreement. According to a recent assessment of the Eli Lilly case, this cross-referencing is dangerous "given the extensive private and public enforcement rights that right-holders already have and given drug companies' proclivities to bring lawsuits against governments."[19] On the same point, Public Citizen argues:

> *Pharmaceutical firms could use the TPP to demand cash compensation for claimed violations of WTO rules on creation, limitation or revocation of intellectual property rights. Currently, WTO rules are not privately enforceable by investors…An Annex in the TPP investment text could empower the three private lawyers of ISDS tribunals, which have a clear track record of interpreting vague terms broadly to favor foreign investors, to impose their binding interpretation of TRIPS' intentionally flexible terms on the very governments that negotiated those terms. This move, which risks making TRIPS obligations enforceable via ISDS, could restrict governments' policy space to ensure access to affordable medicines.*[20]

Intellectual Property (Chapter 18)

To date in Canada, the Intellectual Property chapter of the TPP has probably drawn the most critical attention, though mainly for its copyright, trademark, and other provisions that may affect Canada's tech sector, Internet governance, and privacy rights. The articles in this chapter also cover a variety of areas of importance to pharmaceutical policy such as data exclusivity (ownership of the safety and efficacy data from clinical trials by the company that paid for the trials), patent term extensions (to make up for any delays in processing patent applications or regulatory delays), and a requirement that countries link the marketing approval of generics to the expiration of patents owned by the originating brand-name

company.

Previous federal governments have made concessions on all of these issues in the past; in NAFTA, for example, attached to promises (later broken) by the brand-name drug sector to increase research and development in Canada, and as part of CETA, which has been signed but not yet ratified.[21] But there are some differences between the IP chapters in CETA and the TPP that might affect how much drug costs will increase in Canada if the treaties are ever implemented.

Canada already allows brand-name companies to block the approval of generic competition by alleging the generic company is violating a patent that is still valid. In the CETA negotiations, Canada agreed to reforms that would give brand-name companies the right to appeal in cases where they lose a court case on this issue—a right not included in the TPP. Moreover, CETA appears to extend data protection to non-innovative drugs whereas the TPP does not.

In common, both pending trade deals would lock in additional patent protection beyond the internationally required 20-year term (patent term extension) for delays in marketing approval for new drugs. In the case of CETA, this period could be up to two years, while the length of the extension is not specified in the TPP. In a previous article, Marc-André Gagnon and I calculated that the CETA provisions described above could increase Canadian drug costs by between 6.2% and 12.9% starting in 2023.[22] This was assuming the EU treaty would be ratified first, which is not at all clear at this point.

Because of the differences between CETA and the TPP, if the TPP came into effect first, then Canadian drug costs would initially rise by 5%, since the data exclusivity provisions in the TPP do not cover as wide a range of products as those in CETA.[23] Regardless of timing, both will lock in a specific pharmaceutical strategy of longer patents and stronger brand-name protections for Canada (and all other signatory countries) that cannot be modified in the future without the agreement of all of the other TPP parties.

There is one new provision in the TPP, not present in CETA, which could affect Canadian drug regulation. Article 18.48(4) states the following:

> *With the objective of avoiding unreasonable curtailment of the effective patent term, a Party may adopt or maintain procedures that expedite the processing of marketing approval applications.*

This clause allows for wider use of expedited review processes (i.e., approval mechanisms that are shorter than the standard 300-day process). The likely adverse effect of more rapid approvals on drug safety has already been mentioned.

Transparency and Anti-Corruption (Chapter 26)

This chapter serves the dual purpose of requiring that TPP countries "promptly" publish any "laws, regulations, procedures and administrative rulings of general application with respect to any matter covered by this Agreement," and that they put in place the means to combat corruption in matters related to international trade and investment. An annex to the chapter (Annex 26-A – Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) could have negative effects on pharmaceutical costs and regulation in the future.

The first paragraph of the transparency annex (26-A.1) lays outs a series of principles the parties have to follow, among which are the recognition of "the importance of research and development, including innovation…related to pharmaceutical products," "the need to promote timely and affordable access to pharmaceutical products," and "the need to recognize the value of pharmaceutical products…through the operation of competitive markets."

Innovation, in the pharmaceutical industry's terms, typically means any new therapeutic molecule. Combined with the timely access requirement in the TPP, the term is usually interpreted by industry to mean that any new drug should be listed on public drug formularies as soon as possible after it is approved for marketing.

The principles at the start of the transparency annex are not the same as treaty-level obligations. They are only aspirational statements and not legally enforceable; the parties must only "acknowledge" their importance. As such, they should not pose a problem if Canada were to refuse to approve a product, even if it is a new molecule, or if a provincial drug plan refuses to subsidize a new drug. In the same way, it is unlikely these non-enforceable principles could be used to require provincial plans to make a listing decision within a particular period of time.

While the principles in paragraph 26-A.1 cannot be enforced, the remaining three paragraphs in the transparency annex *can* be (although the formal state-to-state dispute settlement procedures provided for in chapter 28 do not apply to them).

Paragraph 26-A.2 of the annex, on "procedural fairness," deals with how countries set reimbursement prices for pharmaceuticals, requiring them to do so "within a specified period of time," without defining what that might be. If a party cannot complete the review within this time it "shall disclose the reason for the delay to the applicant and shall provide for another specified period of time for completing consideration of the proposal." The same paragraph allows companies to appeal a negative reimbursement decision to either an independent body or to the same expert group that made the original decision (the decision of what appeal mechanism to use is up to the country), provided that the review process includes a substantive reconsideration of the application.

None of the provisions of this paragraph apply to the operations of the Patented Medicine Prices Review Board, as the regulatory body only sets a maximum introductory price for new patented medicines. Nor would the TPP's transparency annex affect the functions of the Pan-Canadian Pharmaceutical Alliance that negotiates prices for brand-name and generic drugs for provincial drug plans. The annex explicitly states, "Canada does not currently operate a national healthcare programme within the scope of this Annex."

However, should Canada, at some point in the future, adopt some form of pharmacare incorporating a system of price regulation then the provisions in this paragraph could apply. But even then, the original decision about prices would not necessarily be overturned, since any review could be done by same governmental body that did the initial review. Importantly, whichever review process is adopted, it is only available for reviewing decisions *not to list* a pharmaceutical or medical device for reimbursement (i.e., it would not apply to pricing recommendations or determinations).

Paragraph 26-A.3 permits pharmaceutical companies to "disseminate to…consumers through the manufacturer's Internet sites…truthful and not misleading information regarding its pharmaceutical products that are approved for marketing in the Party's territory." Companies are already allowed to do this in Canada, and an analysis of FDA warning letters and notices of violations to manufacturers shows that there are serious concerns about online promotion.[24] If a future Canadian government took action to preclude information on websites this provision might be invoked to stop this measure.

Paragraph 26-A.4, on consultation, includes this clause:

> *To facilitate dialogue and mutual understanding of issues relating to this Annex, each Party shall give sympathetic consideration to and shall afford adequate opportunity for consultation regarding a written request by another Party to consult on any matter related to this Annex.*

A similar clause in the Australia–United States Free Trade Agreement (AUSFTA) provoked initial

concerns it could have negative consequences for the way Australia regulates drug approvals and decides on whether or not to fund drugs, but these concerns were not borne out. Consultations *per se* should not present any threat to Canada, especially since the text of this paragraph limits its applicability to issues arising from this particular annex.

The Canadian government could, for example, specify that consultations must take place in an open forum and be chaired by health officials (not trade bureaucrats). The government could exclude industry players outright at this stage. The only obligation in the annex is to consult, with no provisions for making decisions or even offering recommendations.

In the AUSFTA, the Australian government ensured that a non-expert body could not remake the decisions reached by its expert bodies with respect to approvals or funding. The Medicines Working Group that arose out of the AUSFTA has only met twice in the last 10 years and the discussions have been limited to issues arising from the relevant annex of that agreement, so it quickly ran out of things to talk about. Should the Canadian government adopt the same attitude as the Australian government did, consultations pose little threat.

Conclusion

Even from this short assessment of how the TPP might affect the regulation and pricing of medicines, it is clear there is enough in the text to warrant a careful study by Parliament and the public with respect to its impact on public health and the potential to create unnecessary new costs for the public health care system. It is also worth repeating that the U.S. pharmaceutical industry was not satisfied with the outcome of the TPP negotiations, especially with respect to the provisions on intellectual property rights. As a result, it is likely the industry will be very aggressive in pushing for the strictest interpretation of the various provisions of the TPP that relate to medications.

Acknowledgements

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Endnotes

[1] Founding TPP countries include Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. Canada already has free trade agreements in place with four of these countries (Chile, Mexico, Peru and the United States).

[2] For recent estimates of the macroeconomic impact of the TPP on member countries, see World Bank Group (January 2016), *Global Economic Prospects: Spillovers and Weak Growth*, p. 227: "The impact on NAFTA members (all also members of TPP) would be small, on the order of 0.6 percent of GDP, because trade represents a modest share of GDP and because existing barriers to their trade (which is already mostly among them) are already low for the most traded commodities." See also Capaldo, Jeronim and Alex Izurieta (January 2016), *Trading Down: Unemployment, Inequality and Other Risks of the Trans-Pacific Partnership Agreement*, p. 18: "While projected employment losses [from the TPP] are small compared to the labour force, they clearly signal an adverse effect of liberalization not taken into account in full-employment models. In TPP countries, the largest effect will occur in the U.S., with approximately 450,000 jobs lost by 2025. Japan and Canada follow, with approximately 75,000 and 58,000 jobs lost respectively."

[3] At time of writing, the Canada–European Union Comprehensive Economic and Trade Agreement (CETA) is still being translated in the European Union and is not expected to be ratified in either Canada or the EU until the end of 2016 at the earliest.

[4] In this and all instances, citations from the TPP text are taken from the Global Affairs Canada website and adjusted for Canadian spelling. Link: http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/text-texte/toc-tdm.aspx?lang=eng.

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[22] Ibid.

[23] Marc-Andre Gagnon, personal communication, December 2, 2015.

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