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## **Standing Committee on International Trade**

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**EVIDENCE**

**Tuesday, May 31, 2016**

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**Chair**

**The Honourable Mark Eyking**



## Standing Committee on International Trade

Tuesday, May 31, 2016

•(0845)

[English]

**The Chair (Hon. Mark Eyking (Sydney—Victoria, Lib.)):** Good morning, everyone, and welcome back, MPs, from your week in the riding.

As everybody knows, we are the committee for international trade and are a very active committee. We have quite a few things on our plate and we're going to continue. We're dealing with finishing up the European agreement and we have softwood lumber, but right now our focus is on the TPP, the Trans-Pacific Partnership agreement. Our committee has been travelling right across the country. We already did the western provinces, Ontario, and Quebec. In the fall, we'll be doing Atlantic provinces and the territories.

We have had many witnesses. We had open mike submissions at many of the meetings throughout Canada, and we're taking submissions up to the end of June from any individuals. For any MPs who do town hall meetings, we're going to take their submissions up to the end of July. We've also had many people representing companies, organizations, and stakeholders. This is a major agreement, as many of you around this table know, and it's going to affect every Canadian one way or another, whether you're a consumer or a supplier.

Today, our main theme is the health care system. We have many representatives here from various sectors of the health care system.

We're doing this a little differently today. Around June, things get a little active around Ottawa. Well, they're always active, but around June things get a little unpredictable. What we're going to be doing now in our committee meetings is having all the witnesses do their presentations, and then we'll have a dialogue with MPs as long as we can. I feel that this is better, because our main objective in our committee is to listen and to hear what Canadians and people involved in the different sectors have to say.

If something happens, we may adjourn. As members of the House, if we have to go into the House, we will, but it doesn't look like there's anything that's going to interrupt us this morning.

Without further ado, we have six witnesses, and we have somebody all the way from Norway.

Can you hear me in Norway, Mr. Labonté? I'll start with you.

**Mr. Ronald Labonté (Professor and Canada Research Chair in Globalization and Health Equity, University of Ottawa, Canada Research Chairs Program):** Yes, I can, thanks, very clearly.

**The Chair:** Before you start, we're asking each witness to keep it around five minutes. We'd appreciate it. If it's a little shorter, that's fine, or a little over, but get your point across, and then we'll have a lot of dialogue with the MPs as we go forward.

Go ahead, sir. Welcome.

**Mr. Ronald Labonté:** Thank you very much and thanks for the opportunity to address you from the rather lovely city of Trondheim, Norway.

I direct the globalization and health equity research unit at the University of Ottawa. We recently completed a two-year health impact assessment of the Trans-Pacific Partnership agreement. I'm going to speak to a few of our findings.

First, the TPP's impact on the cost of pharmaceuticals has received considerable attention. I know the committee has already heard from Dr. Joel Lexchin, whose earlier work on CETA's patent term extensions estimated the drug costs in Canada by 2023 could rise by between \$2 billion and \$3 billion, without guaranteeing any therapeutic gains.

The TPP locks in these provisions while also loosening requirements for evergreening of patents. It's important to put this into the context that meanwhile, a UN high-level panel is calling for new models for the development of health technologies and drugs that go beyond patent regimes to better balance trade and industry interests with human rights and public health concerns. So increasing pharmaceutical patent provisions appears to be somewhat out of step with these other multilateral discussions on ensuring access to life-saving drugs.

Second, although the TPP does not significantly change the single-payer model of the Canadian health care system, there are new risks. Canada already liberalized private health insurance under the GATS and under NAFTA, so should Canada extend public health insurance monopoly into areas where foreign-invested private insurance has interests, this could trigger a dispute. The TPP adds to this risk by extending investor-state rules to a much larger number of foreign investors and exposes claims over private health insurance to the rather controversial FET provisions in ISDS, which are not part of NAFTA, at least not part of NAFTA's financial services chapter.

Investor health insurance related claims against other countries have actually already occurred and succeeded under bilateral investment treaties with similar provisions to those in the TPP. While it's true that Canada's annex II social services reservation could offer protection against such an investor suit, this would very much depend on the tribunal's interpretation of that reservation.

Third, and an important public health gain, is that the TPP does allow a voluntary exclusion from investor-state claims against tobacco control measures. This exclusion does not apply to state-to-state disputes that could arise following pressure from tobacco interests within TPP member nations, nor does it prevent tobacco transnationals from using other investment treaties, such as NAFTA, to launch investor-state claims against Canada over new tobacco control measures, which could include Canada's commitment to plain packaging.

The exclusion nonetheless importantly signals that TPP governments were concerned with the potential impact of ISDS provisions on public health regulations, which really begs for us the larger question: Why was this exclusion not extended to all non-discriminatory public health measures a country might adopt, especially given the impact of other globally traded health-harmful products, such as ultra-processed foods and alcohol?

Fourth, the TPP creates new barriers to regulate these health-harmful commodities. New provisions in its SPS and TBT chapters could weaken use of the public health precautionary principle, which is applied when there is insufficient evidence for a scientific consensus on health risks, and at the same time require TPP parties to ensure that any new regulatory standards do not create unnecessary obstacles to international trade. These provisions could strengthen trade interests over efforts to regulate for consumer, public, and environmental health. The TPP also creates avenues for vested corporate interests to influence the development of such standards.

TPP governments have responded to some of these concerns by pointing to the TPP's health exceptions. These include the use of the WTO's GATT article XX(b), which allows governments to enact measures necessary to protect human health, amongst others, that are not judged to be unjustifiable discrimination between countries. This is an important exception, but so far, it has only been successful in one of 43 cases, with most of the cases failing on the necessity test, meaning that dispute panellists believe there were less necessary options in terms of trade that could have been pursued.

The general exception in the ISDS chapter similarly allows parties to adopt measures to achieve environmental health or other regulatory objectives, but quickly adds that this is only if these are otherwise consistent within the chapter.

● (0850)

**The Chair:** Sir, I'm sorry. Could you make some concluding remarks, please.

**Mr. Ronald Labonté:** Sure.

Generally speaking, we don't believe there is sufficient protection for public health regulation now and into the future existing within the TPP, and neither do we find any evidence of some of the health-enhancing or health-promoting opportunities related to economic

growth, jobs, or employment. None of the economic studies we have seen actually indicate that those gains, if any, would be substantial.

It's hard to see how the TPP represents any health benefits. We believe it also poses significant health risks.

Thank you.

**The Chair:** Thank you, sir.

We'll move now to Innovative Medicines Canada. We have with us Declan Hamill and Mark Fleming.

Go ahead, for five minutes.

**Mr. Declan Hamill (Chief of Staff and Vice President, Legal Affairs, Innovative Medicines Canada):** Thank you.

Mr. Chairman, I'm pleased to be here today as part of the trade committee's consultation on the Trans-Pacific Partnership agreement.

With me is my colleague Mark Fleming from Janssen Pharmaceutical Companies of Johnson & Johnson.

[*Translation*]

Innovative Medicines Canada is the national organization representing innovative pharmaceutical companies in Canada. We are dedicated to enhancing the well-being of Canadians through the discovery and development of new medications and vaccines. Together, we invest over \$1 billion in research and development annually, fuelling Canada's knowledge-based economy.

[*English*]

We'd like to briefly address a number of what we believe are misconceptions about how the provisions of TPP will impact Canadian pharmaceutical innovation, Canadian patients, and the costs to health care in Canada.

The first claim is that TPP somehow represents a significant increase in Canadian life sciences intellectual property protections.

Mr. Chair, in Canada's technical summary of negotiated outcomes of the TPP, the federal government concludes that on pharmaceuticals, TPP outcomes are, "In line with outcomes secured in the Canada-EU Comprehensive Trade and Economic Agreement (CETA)". In other words, TPP breaks no materially new ground in extending IP protection in life sciences beyond what was negotiated in CETA.

The second claim that's often heard is that TPP will extend the life of patents in Canada.

Mr. Chair, under TPP, patent terms will remain at the international standard of 20 years. What will happen is that innovative companies will have an opportunity to potentially recover some of the time lost on their patents as a result of lengthy clinical trials and regulatory approval process delays.

The third claim is that TPP will increase the cost of Canadian medicines.

Mr. Chair, IP protection does not drive the cost of new medicines and vaccines. Besides, nothing in the TPP will prevent Canadian federal, provincial, and territorial governments from doing exactly what they do now, which is to set pharmaceutical prices through the PMPRB and other federal, provincial, and territorial price-setting mechanisms.

• (0855)

**Mr. Mark Fleming (Director, Federal Affairs and Health Policy at Janssen Inc., Innovative Medicines Canada):** The fourth claim made by TPP critics is that the Canadian system already provides sufficient intellectual property supports for life sciences competition and innovation.

Mr. Chair, in the life sciences context, patents and data protection act as incentives for biopharmaceutical companies to make enormous R and D investments necessary for new innovative medicines. New medicines cost on average \$2 billion to develop, and take 10 to 15 years through the regulatory research and development pathways, yet Canada affords less IP protection than its G7 counterparts and many other industrialized countries provide.

The intellectual property provisions agreed upon through the CETA negotiations between Canada and Europe do take very positive steps in helping to level the playing field between Canada and the EU and other developed countries around the world. For example, since the first announcement of CETA in 2013, my company, Janssen, has committed \$1 billion in life sciences investment to Canada.

The IP provisions in CETA were not the only impetus for this investment, but they were certainly a critical catalyst toward enabling us to put Canada on the global investment radar screen of our company. Included in these investments are some living examples, such as the recently launched, on May 11, JLABS @ Toronto, which will house up to 50 Canadian life sciences innovators, removing the financial barriers that start-ups face in making their discoveries and helping them to do what they do best: discover, invent, and create life-saving technologies.

But to reiterate, that's CETA, and this panel is exploring TPP. We believe TPP will have little, if any, impact on Canada in regard to pharmaceutical IP, and is largely in line with what this country already has in place and what is already agreed to in the CETA text.

We would draw the committee's attention to a recent article by my colleague Mr. Hamill that Mr. Barry Sookman tabled in his appearance before this committee a few weeks ago. It provides a more fulsome analysis of the basic provisions of CETA, TPP, and the various IP provisions of Canada and its major trading partners.

To sum up, Mr. Chair, as a matter of principle our association supports international trade agreements that help build Canada's

economy. As Canada grows, we will continue to invest, continue to innovate, and ensure that patients have access to life-saving and life-improving medicines.

Thank you very much. *Merci.*

**The Chair:** Thank you, gentlemen.

We're going to move over to the Canadian Nurses Association. We have with us Carolyn Pullen.

Go ahead.

**Dr. Carolyn Pullen (Director, Policy, Advocacy and Strategy, Canadian Nurses Association):** Thank you for this opportunity.

I'm a registered nurse and one of 139,000 members of the Canadian Nurses Association.

By now the committee is well versed on the arguments for and against Canada's ratification of the TPP. Today I highlight the reasons the CNA recommends against ratification, reinforcing some concerns that have been raised previously by others and highlighting considerations specific to the nursing profession in Canada. The CNA advocates for Canada's publicly funded health system. We maintain that ours is the best model for promoting the health of all Canadians and providing universal access to high-quality care, regardless of ability to pay.

The economic impacts of the TPP for Canada have been estimated to be relatively small, potentially as low as 0.1% of GDP by 2035. While there may be benefits for some sectors, the deal has potentially serious implications for how health systems are governed, posing threats to the evolution of Canada's health system and affecting all Canadians.

The CNA has the following four concerns:

First, under TPP the cost of drugs would increase, and implementing a national prescription drug program, a program most Canadians support, would be less feasible. Through extending drug patents, delaying the availability of less expensive generic medicines, by 2023 Canada would see an annual cost increase of up to \$636 million, or 5% of the annual cost of patented drugs in Canada. There would be a concurrent negative effect on global health due to the unaffordability of these life-saving medicines.

Second, through the TPP investor protections and investor-state dispute settlement, ISDS, mechanism, privatized health services would effectively be locked in, and future expansion of Canada's public health insurance would be impeded. Of particular concern is the potential for the ISDS to interfere with expansion of public health insurance to areas currently insured by private providers. Pharmacare is one example.

Third, the TPP would pose challenges to Canada's ability to regulate health services. The TPP section on cross-border trade in services includes reservations for health services but fails to exclude ancillary services, such as food, cleaning, maintenance, computer and data management, hospital administration, and other critical supports. Where such services are privatized, attempts to re-regulate or to return them to the public sector could be exposed to legal challenges under the TPP.

Specific to the nursing profession, as of 2015 the new entry to practice registration exam for nurses is the American NCLEX RN exam, a product of the National Council of State Boards of Nursing, or NCSBN, a U.S. private organization. Consequently, measures regulating the testing and training services provided by this U.S. vendor would fall outside the scope of the annex II reservation.

There are a number of serious concerns with this exam, including poor translation of the French exam, a paucity of preparatory materials for francophone students, lack of alignment between the exam and competencies required for nursing in the Canadian health care system, and a negative impact on the numbers of eligible graduates entering the workforce.

If provincial governments or the regulatory bodies move to address these concerns, complaints by NCSBN could result in a government-to-government or investor-state dispute under TPP. To avoid this costly scenario, the problems with the NCLEX may remain unaddressed, leaving the development of Canada's largest health workforce, nursing, subject to policy lock-in and regulatory chill, as has been raised previously with the committee.

Finally, the TPP would impede expansion of the public health system to include programs such as pharmacare. The transparency annex gives new rights to brand-name companies to contest the decisions of public drug agencies, tilting toward market-based pricing and increasing costs to governments.

The annex explicitly states that Canada “does not currently operate a national healthcare programme within the scope of this Annex”. Consequently, if Canada developed a future national health care program covering drug pricing and reimbursement, it would come under pressure to comply with the transparency annex. This chapter would prevent the federal government, the fifth largest health services provider in Canada, from getting the best therapeutic value for taxpayers' money. The transparency annex could also hamper Ottawa's future ability to co-operate effectively with provincial and territorial governments in joint measures, such as a national formulary, to make drugs more affordable.

It is for these reasons that the CNA calls for the federal government not to ratify the TPP.

Thank you for your time today.

• (0900)

**The Chair:** Thank you.

Now we're going to move over to the Canadian Generic Pharmaceutical Association. With us today we have Jim Keon and Jody Cox.

Go ahead, folks.

**Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association):** Mr. Chair, on behalf of the Canadian Generic Pharmaceutical Association and our member companies, I'd like to thank you and the other honourable members for this opportunity to participate in the study of the TPP.

As you mentioned, I'm joined today by Jody Cox. She's our vice-president of federal and international affairs. Jody was very active in attending TPP rounds and representing the views of our industry in Canada and internationally.

Our generic pharmaceutical companies directly employ more than 10,000 Canadians in highly skilled research, development, and manufacturing positions. We operate the largest life sciences companies in both Ontario and Quebec. We are Canada's primary drug manufacturers and exporters, and are among the top R and D spenders across all industrial sectors.

The generic pharmaceutical industry is a strong supporter of free and open trade. We export high-quality made-in-Canada generic medicines to more than 115 countries. We also procure raw materials and other inputs from around the world.

Our industry provides tremendous value to the Canadian health care system. Generic medicines are dispensed to fill 69% of prescriptions—basically seven out of 10 prescriptions in Canada are filled by generics—but account for only 22% of the \$25 billion Canadians spend annually on prescription drugs.

I want to say a few words about pharmaceutical IP and trade before talking specifically about the TPP. We know your committee is studying the TPP. The pharmaceutical IP provisions need to be considered, however, in a broader context.

First, it is important to recognize that Canada had strong intellectual property protection for pharmaceuticals before either the CETA or the TPP negotiations. When the CETA negotiations were under way, the average length of market monopoly protection for brand-name drugs in Canada was estimated to be six months longer than in the U.S.

The second context point I'd like to make is that the pharmaceutical outcomes in CETA were concessions made by the Government of Canada to get the deal done. These were demands made by the Europeans on behalf of brand-name pharmaceutical companies that have their headquarters in Europe. They were not done to spur innovation in Canada. They were done to get the CETA deal finished. Research into new drugs is done as part of global development programs. Decisions about where to site R and D have little or nothing to do with intellectual property, as a large number of originator R and D investments in India and China help to underscore. An educated workforce, low business costs, and other factors drive these decisions.

The third context point I'd like to make is that major changes to Canada's IP system for pharmaceuticals are going to be required to ratify the trade agreements. The changes will have significant cost implications for the Canadian health care system. I'm not going to get into the numbers today, but the specific costs will depend on the way it's implemented.

I would note as well that you had before you an assistant deputy minister at Health Canada who spoke to the question of increased costs. Actually, it was not this committee; it was the health committee. She spoke to the impact of CETA on health care costs. The PMPRB controls the price of patented medicines, but if you can't buy a generic medicine at a fifth of the price, clearly costs are going to go up. As we extend patents, costs will go up.

New IP measures will also have an impact on Canadian generic pharmaceutical companies. Our companies are part of global supply chains and are active in competition to bring investments and jobs to Canada. In order to operate in this environment, companies need to be able to access export markets for new generic medicine as soon as they open up to competition. Being late to the game generally means a permanent lost potential market share that can never be recovered.

Generic pharmaceutical companies must navigate the domestic pharmaceutical intellectual property system in order to manufacture both its domestic and its export markets. We will lose out on investment in Canada if the legislation is not kept at a competitive pro-trade level.

I will say a couple of words on the TPP outcomes. Overall, the TPP text for pharmaceuticals is about increasing intellectual property beyond the existing levels in the TRIPS agreement administered by the World Trade Organization. Despite that, the final TPP outcome that was negotiated by Canadian officials on pharmaceutical IP is intended to be consistent with the extra commitments that Canada had already made under CETA.

Under CETA and the TPP, Canada has agreed for the first time to extend the term of pharmaceutical patents, ostensibly to take into account the time brand-name drugs spend in the regulatory approval process. It is important to note that the extension is to be capped at two years.

● (0905)

**The Chair:** Could you make some conclusions. Thank you.

**Mr. Jim Keon:** Yes.

Another important aspect is that there will be an export provision allowed in the TPP during the extension period.

I think one of the things we would say is that how the implementation of the TPP is done will be critically important, and Minister Bains' department, the Department of Innovation, Science and Economic Development, will be critically important.

The last point I would make is that the TPP and CETA do extend patents for pharmaceuticals and will have costs and some implications for the generic pharmaceutical industry.

**The Chair:** Thank you.

We'll move over to CropLife Canada and hear from Dennis Prouse. Go ahead, sir. You're no stranger to the committee room. It's good to see you.

**Mr. Dennis Prouse (Vice-President, Government Affairs, CropLife Canada):** Thank you, Mr. Chair.

I appreciate the committee having me here today. I know I'm a bit of an outlier from your theme in that I'm with agriculture with, I guess, a bit of a connector back with biotechnology, but I appreciate your generosity in having me here today.

CropLife Canada is the trade association representing manufacturers, developers, and distributors of plant science innovations, including pest control products and plant biotechnology for use in agriculture, urban, and public health settings. We're committed to protecting human health and the environment and believe in providing a safe, abundant food supply for Canadians. We believe in driving innovation through continuous research.

CropLife Canada is a member of CropLife International, a global federation representing the plant sciences industry in 91 countries. Our mission is to enable the plant sciences industry to bring the benefits of this technology to farmers and to the public. Those benefits manifest themselves in many different forms, including sustainability, driving agricultural exports, job creation, strengthening the rural economy, and increased tax revenue for governments.

Canada is a trading nation and in no other sector is that more true than in agriculture. Canada enjoyed a surplus of close to \$12 billion in agrifood trade in 2015. This is very positive not only for the Canadian economy, obviously, but for Canada in the leadership role we can play in feeding a growing world population.

This surplus is made possible by two broad policy pillars. First, it's supported by a science-based regulatory system that allows farmers to stay modern and competitive. It provides a stable, predictable regulatory framework based on sound science rather than politics, at least at the federal level, and it ensures that our farmers have access to the innovative tools of modern agriculture they need to be sustainable and productive.

The second pillar of Canadian agricultural success is international trade agreements that secure market access for Canadian products. CropLife Canada and its member companies are strong supporters of both the CETA, the agreement with the European Union, and the Trans-Pacific Partnership being discussed today. These two initiatives hold the promise of access to robust, prosperous, and growing markets for Canadian agricultural products.

TPP member countries represent over 65% of Canada's agrifood exports. Guaranteeing access to these markets is vital, given that Asia will represent two-thirds of the world's middle class by 2030 and half of global GDP by 2050. Put plainly, Canada's future competitiveness depends on agreements like the TPP.

Eliminating tariffs is obviously a very desired outcome. One issue I do wish to stress with the committee today, however, is that of non-tariff trade barriers. This is an issue of deep concern both to our members and their customers, Canada's farmers. Many agricultural exports face a daunting number of non-tariff trade barriers, such as trading rules on biotechnology, sanitary, and phytosanitary products. Rules on low-level presence of biotech crops and non-biotech shipments are an example of the former, and rules on maximum residue limits of pesticides on fruits and vegetables and all exported commodities would be an example of the latter.

In both instances we've seen arbitrary non-science based rules imposed by other nations act as a proxy for tariffs in preventing imports. As other witnesses before this committee have noted, the fall of tariffs around the world are often quickly accompanied by a rise in non-tariff trade barriers. In addition, there are cases where non-tariff trade barriers are not deliberate. There are many countries that clearly have no defined mechanism to establish an import maximum residue limit, or their process is not harmonized with Canada in terms of science or process.

It illustrates the need for both transparency and a rigorous dispute settlement mechanism in any trade agreement, one based on sound peer-reviewed science. Fortunately, the TPP has some clear wins on the issue of science-based regulation to accompany the tariff reductions. Transparency in decision-making is built into the agreement, as is a dispute settlement mechanism that has science-based regulation as a key component. The TPP will also specifically address the issue of low-level presence in shipments. This makes the science-based regulatory provisions of TPP significantly superior to those found in CETA.

Should we move forward on the TPP, it will be incumbent on Canada and all other nations with a science-based regulatory system to be vigilant on this issue and further clarifications in negotiations.

As you can see, Mr. Chair, our members are strong free traders. We know that trade and innovation are the two key pillars to growth and prosperity in Canada and that the TPP supports both of these

pillars. The GrowCanada partnership, which represents all of Canada's major grower groups and of which we are a proud member, sees export growth as a key to prosperity for Canadian farmers, which is why you will see strong support for the TPP among every major grower group in Canada.

● (0910)

Across Canada nine out of every 10 farms are dependent on exports. This represents 210,000 farms, and includes the majority of farms in every province. Canada's food processing sector employs a further 290,000 Canadians.

To conclude, Mr. Chair, we see that the TPP is a tremendous step forward, and it's a statement of confidence in the future of Canadian agriculture. We would urge the Government of Canada to ratify the TPP and show leadership in encouraging other countries to do the same.

Thank you.

● (0915)

**The Chair:** Thank you, sir.

We're going to move on to the Canadian HIV/AIDS Legal Network. We have with us Mr. Richard Elliott. Go ahead, sir.

**Mr. Richard Elliott (Executive Director, Canadian HIV/AIDS Legal Network):** Thank you, Mr. Chair.

Thank you to the committee for the invitation to appear.

I am the head of an organization that 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 member of a larger coalition of organizations that are concerned about access to medicines. A copy of the submission that has been distributed to you, I believe, includes the names of a number of organizations that have shared those concerns with you.

Last, I should mention that I am a member of the expert advisory group to the UN Secretary-General's High-Level Panel on Access to Medicines, which was mentioned by Professor Labonté before, although obviously I don't appear on behalf of that panel today.

We have a number of serious concerns with the TPP, and I want to focus on two aspects of the TPP in particular: the chapter on intellectual property, and the chapter on investment, both of which have already been mentioned. Our concerns are also about both the domestic impact and the international impact of this agreement, which has been quite properly characterized as TRIPS-plus, that is, exceeding the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization.

On the domestic front, the provisions in both the IP chapter and in the investment chapter will lock in, and in some cases make even more restrictive, the IP rules that already exist in Canada which will further delay access to lower cost medicines. Very importantly, as you've heard from the CNA and from Professor Labonté, this will chill regulatory innovation for public health, including in particular, the potential for expanding our public health insurance to include a national pharmacare program with some form of price regulation, something that has been recommended for decades in Canada by many different parties, and by many different commissions and studies, and yet hasn't moved forward.

The TPP will actually make that more difficult, and the longer we don't have a domestic pharmacare program and take advantage of our ability to regulate in the public interest, the longer we'll continue to have inequitable access to medicines in Canada.

If the impact on Canada and Canadians is important, it's even more significant for developing countries that aren't fortunate to have the same resources that a high-income country like Canada has. For countries in the global south, the TPP member states that are low- or middle-income countries will in fact have to adopt significant new restrictive measures related to intellectual property that will have a negative consequence on access to affordable medicines.

Given that the TPP has been presented as a template for future trade agreements, this can't be ignored. It's not simply the handful of low- and middle-income countries that will be most immediately affected by the TPP in this way, but it's also the pressure that will then arise on other countries similarly situated in the future in other trade negotiations. There has been no secret made of the fact that this is the plan for the TPP.

I want to remind us, as a matter of context, that 15 years ago all the member states of the WTO, including Canada, adopted a declaration that was aimed at preserving the flexibility that countries have in shaping their public policy in order to improve access to affordable medicines for all, including a number of measures that, in some cases, will be made more difficult by the TPP.

It's a bit strange that when you have a declaration that has been adopted by Canada and all the other WTO members, against the backdrop of a global AIDS crisis and millions of people dying of AIDS and of other illnesses in developing countries, where we say that we'll preserve the policy space and the flexibility that countries have, but then at the same time we negotiate other trade agreements that will chip away at that policy space and that ability to regulate in the public interest, that doesn't seem like acting in particularly good faith.

I should also note that Canada, of course, is a significant contributor of funds to global health initiatives, including through the Global Fund to fight AIDS, TB, and Malaria. In fact, Canada will be hosting the next replenishment conference of the Global Fund later this year. We should stop to think about the Canadian taxpayer dollars that are being contributed to such an important, health-financing mechanism that has saved millions and millions of lives around the world, but whose ability to save those lives will be impeded when the prices of medicines are actually kept unaffordable. If we're going to contribute money to try to save lives by making medicines affordable, let's not at the same time chill the

ability of countries to actually control the prices of those medicines. In doing so, we limit the effectiveness of our foreign aid.

Specifically with respect to the two major areas of concern regarding access to medicines in the TPP, the first is the question of the provisions on intellectual property, in the intellectual property chapter of the TPP, and in particular—

• (0920)

**The Chair:** Sir, try to make some conclusions. I'll give you another half a minute, if you can do it.

Go ahead, sir.

**Mr. Richard Elliott:** —the extension of patent terms beyond what already exists, which will apply in both Canadian and other TPP member states; the locking in of our linkage regulations that tie marketing approval of generics to claims of patent infringement by brand-name companies; and provision that the Supreme Court of Canada has already declared to be draconian would be locked in by the TPP, locking in data and market exclusivity provisions, and so on. Those will all have a negative impact on Canadians' access to medicines and also those of people in developing countries.

You've already heard about the regulatory chill that will be created by the investment chapter, the provisions of which now explicitly for the first time apply to IP provisions. Canada should take particular note of the fact that Canada is the subject of the first investor-state dispute settlement provision by a pharmaceutical company under NAFTA. We are now taking those provisions and globalizing them further through the TPP.

Instead of going down this route, we could take a number of positive approaches. I'll wrap up with a couple of suggestions.

The High-Level Panel on Access to Medicines that the UN Secretary-General has struck is looking at how to come up with better policy approaches for both more innovation and better access, rather than the skewed innovation and limited access we have now. We could instead be active participants in negotiating a global health R and D treaty that would address public health needs of the world, and we could instead be negotiating treaties that guarantee policy space for countries to protect public health, as we said 15 years ago we were hoping to do.

Thank you.

**The Chair:** Thank you.

Before we open up the dialogue with the MPs, I'd like to recognize Mr. Ruckert. You're a colleague from the University of Ottawa with Mr. Labonté. It's good to see you here. You're also available to take any questions from us.

It's also good to see my old buddy Mr. Shipley here.

**Mr. Bev Shipley (Lambton—Kent—Middlesex, CPC):** Mr. Chair, yes.

**The Chair:** He taught me all. He was my former chair, so any bad habits I have come from him.

**Some hon. members:** Oh, oh!

**Hon. Gerry Ritz (Battlefords—Lloydminster, CPC):** All of them?

**Some hon. members:** Oh, oh!

**The Chair:** Not all of them, but some of them.

It's good to see you here, Mr. Shipley.

I'll just remind MPs that because we have such a large panel here, try to keep your questions tight and short, because you might have different panellists wanting to answer your questions. There's a good chance we're going to have a second round for you anyway.

Without further ado, we'll get going.

The Conservatives are going to start us off for five minutes.

Mr. Ritz, you have the floor.

**Hon. Gerry Ritz:** Thank you, Mr. Chair, and thank you, ladies and gentlemen, for your presentations today.

I'm more confused than ever. I sit here listening to pharmaceutical companies saying they're not concerned about the TPP, and yet I hear from a lot of other people who say they should be. I guess one of you is being tricked.

I want to start with Mr. Labonté. If I remember correctly, in your opening remarks, you forecasted an increase of \$2 billion to \$3 billion in pharmaceutical costs by 2030. Did I get that right?

**Mr. Ronald Labonté:** You got that partly right. It was fully in force by 2023 under the CETA provisions. Those are not my figures. Those are the figures Dr. Joel Lexchin and his colleagues came up with when they did a cost estimating future under the provisions of the CETA.

**Hon. Gerry Ritz:** Sure. Seven or eight years out we're looking at an increase of \$2 billion to \$3 billion. What has the increase been for the last same amount of time? I think if you did that analysis you would also find that pharmaceuticals have gone up roughly \$2 billion to \$3 billion. There's a natural increase year over year. There's a little thing called inflation, and cost of production, and so on.

**Mr. Ronald Labonté:** There was one figure we had in one of our presentations, which I don't have in front of me, so I don't have the data before me. It showed that over a period of time the price per pharmaceuticals for the patented or brand-name pharmaceuticals has risen, while the price for generics has fallen. That's been a consistent pattern in Canada for the last number of years.

**Hon. Gerry Ritz:** You're saying that will drastically change once the TPP is implemented.

**Mr. Ronald Labonté:** It will change if CETA is ratified, and the TPP will lock in those provisions and probably add one or two additional ones, which may make it a bit more difficult.

**Hon. Gerry Ritz:** You're not in favour of either CETA or the TPP, simply from that standpoint.

**Mr. Ronald Labonté:** Yes. The comments that were made earlier that the TPP doesn't substantially change what Canada's commit-

ments are is largely correct, because the TPP commitments around patents very much follow on from what Canada has already agreed to under CETA.

**Hon. Gerry Ritz:** Okay. Thank you.

The one thing I would pose to all of the witnesses is that the provinces are the administrators of health care. There are health care transfers from the federal government. They're the ones that administer it, and yet all of the provinces are in favour of CETA and the TPP, and they're looking at it in balance. What advice would you give to them moving forward with TPP?

Yes, Jim.

• (0925)

**Mr. Jim Keon:** Thank you. I have a couple of comments.

Actually, drug spending in Canada has not increased over the past number of years. That's primarily due to what was called the patent cliff. A number of large brand-name medicines lost patents a few years ago, and when the generics came on the market at 18% or 25%, that reduced costs.

The other thing about CETA is that I think the government actually acknowledged that there were going to be increased costs to the provinces and had agreed to fund those extra costs through extra transfer arrangements.

**Hon. Gerry Ritz:** Should they appear, yes.

**Mr. Jim Keon:** Yes. I think it's important that.... Again, to come back to my comment about the implementation, these costs will appear only in the future if the agreement is implemented properly. That means patent extensions should not apply to drugs already on the market. They are only to apply to new drugs that come on the market after the agreement enters into force. I think that's critical.

**Hon. Gerry Ritz:** Yes, absolutely.

Also, to your colleague, Ms. Cox, Jim mentioned that you attended a lot of the negotiation panels and so on, yet they were all done in secret, so were you just stuck in a closet somewhere and not taking part?

**Ms. Jody Cox (Vice President, Federal and International Affairs, Canadian Generic Pharmaceutical Association):** No, I was certainly not sitting in a closet. During the negotiation rounds, we did seek meetings with various negotiators from various countries, and of course with the Canadian negotiators, including Minister Fast himself, during many negotiating rounds. There was that ability to meet with various countries and share perspectives in terms of the TPP, the potential text, and what good outcomes could be in terms of—

**Hon. Gerry Ritz:** In fact, there were a number of people who took advantage of the non-disclosure clauses and were very active, just like you, in the negotiations and in being brought up to speed as to what was happening and giving advice.

**Ms. Jody Cox:** Yes, certainly, seeking out those opportunities ourselves, absolutely....

**Hon. Gerry Ritz:** Ms. Pullen, I—

**The Chair:** You only have 15 seconds left, Mr. Ritz.

**Hon. Gerry Ritz:** Okay. I'll pass, then, and we'll move on to the next one.

**The Chair:** We're going to move to the Liberals for five minutes.

Go ahead, Mr. Dhaliwal.

**Mr. Sukh Dhaliwal (Surrey—Newton, Lib.):** Thank you, Mr. Chair.

First of all, I'd like to thank each and every one of you for bringing in very diverse views here.

Ms. Pullen, you noted that the ratification of the TPP would make it less feasible to implement a national drug program. Could you explain why?

**Dr. Carolyn Pullen:** As you have heard around these tables, the majority of Canadians are in favour of a national pharmacare or prescription medication program.

We have also been active in other committees that have been studying a national pharmacare program. In our observations and analysis of the TPP and in looking at the analyses of others, what we have been able to conclude is that the impact of the TPP on escalating drug prices, and also the regulatory chill that could be imposed by the TPP which might prevent negotiation within Canada of things such as a single national formulary for drugs, are factors that might prevent Canada's ability to proceed with a national pharmacare program.

**Mr. Sukh Dhaliwal:** Thank you.

For all the witnesses who want to contribute to this next question, we had Mr. Michael Geist at this committee, who has been a very vocal critic of the TPP. He has said that the drug prices can escalate and that research and development funding is going to go down and increasing this pattern in the TPP will only further amplify these problems. Do you agree or disagree? Would any one of you want to respond?

Yes, please, Mr. Fleming.

**Mr. Mark Fleming:** Yes. Thank you for the question.

First of all, I think it's important to recognize that any changes in intellectual property are enshrined in CETA, the agreement between Canada and Europe. The TPP mirrors CETA. If and when CETA is ratified, that meets the requirements for the Trans-Pacific Partnership agreement.

I bring up CETA because it's important to look at the European health care systems and compare them to the Canadian health care systems. Currently, Europe has a more robust intellectual property regime than Canada does, and yet Europe does not experience significantly increased drug costs in that environment. In fact, their overall health care costs and their percentage of drug costs as part of their overall health care costs are lower than what we're currently at here in Canada. It's a misnomer to think that intellectual property changes will in fact increase drug prices.

What we are experiencing, from our company's perspective, is that we're able to leverage the changes that are forthcoming in CETA to help attract research and development investment to our country. I chair the committee for inward investment for my company, and I know that we have been able to leverage that at our head office to

attract, as I mentioned earlier, over \$1 billion of life sciences investment in the last two years. That's keeping Canadian jobs in Canada.

• (0930)

**The Chair:** Mr. Elliott and Mr. Keon can answer that if their answers are quick.

Go ahead, Mr. Keon.

**Mr. Jim Keon:** Very quickly I'd like to make a distinction between drug prices and drug costs. Drug prices won't necessarily go up; drug costs will go up. When you have to buy a product at 100% of the cost of a brand-name product instead of 18¢ or 25¢ for a generic, for an extra two years, that drives up costs. I think we should be clear on the terminology. Clearly costs are going up. R and D by research-based companies is at a historical low in Canada despite many increases in intellectual property over the last two decades.

The third thing is that I'm very pleased to hear that CETA and the TPP have the same provisions indicated by Innovative Medicines Canada. We've seen, however, pressure on other countries that are trying to do what Canada is trying to do. For example, New Zealand has said it wants a two-year patent extension. The brand-name pharmaceutical industry internationally is saying that's not good enough under the TPP and they expected much more than that.

I think we should all remember that in Canada, the two-year patent extension under CETA meets our TPP commitments as well.

**The Chair:** Mr. Elliott, could you give us a quick answer on that one?

**Mr. Richard Elliott:** Yes. I have two quick points.

It's important to remember that one of the commitments made by the originator pharmaceutical industry when NAFTA was adopted with more stringent IP provisions and less policy space for Canada was that they would commit to 10% of sales spent annually on R and D.

Interestingly, according to the figures reported by the Patented Medicine Prices Review Board for the first period of time and until the review of NAFTA that was mandated by law was completed, those commitments were met. The minute that review was completed and every year since then, they have consistently dropped. So the notion that somehow adopting ever more stringent IP provisions will necessarily translate into more R and D certainly hasn't been borne out in Canada's experience with NAFTA.

The second point I would make is that if, as we've heard, the IP provisions in the TPP aren't really anything particularly new or different, then why have they been negotiated for so hard? If that's true, there shouldn't be that much opposition to removing them, if they don't actually add that much. I suspect the answer is that they are seen by the originator pharmaceutical industry to be giving them something of significant benefit and that's why they're there.

**The Chair:** Thank you, Mr. Elliott.

We're going to move to the NDP now.

Madam Ramsey, go ahead.

**Ms. Tracey Ramsey (Essex, NDP):** Thank you so much.

Your presentations have been just fantastic, and unlike my colleague, I won't say that you're trying to trick us. I think you represent different views, and certainly we've heard concerns across this country about pharmaceutical costs.

I'd like to address my first question to Ms. Pullen.

You represent nurses, front-line health care professionals. I know that in my community, people cannot afford their medication as it is. People are skipping doses. People are not able to afford their medication whether or not they have extended health care coverage, so when there is an increase in the costs...

I thank Mr. Keon for highlighting to us that this is an increase in the costs. It's not an increase in individual drug prices; it's the cost over the period.

If we're talking about the costs and about patients not being able to afford their pharmaceutical drugs, can you speak to us about the health outcomes for Canadians who are unable to afford their medication?

**Dr. Carolyn Pullen:** Thank you for that question. It's an important component of this discussion.

My personal strength is not in economic analysis. What we've been able to bring to the table are the unbiased and non-business interested analyses by other groups. These analyses are those in which we have trust. When we cite increasing costs or our drug prices, we are relying on those analyses and we perceive that the consequences of the TPP and potentially other agreements are severe.

At the front line, every day nurses see individuals not filling prescriptions or they are skipping doses of medications. The numbers have been cited as being in excess of one in five Canadians or as low as one in ten, but that's still significant. That translates into higher costs for managing chronic disease in Canada, more admissions to hospital, longer lengths of stay, and essentially poorer health outcomes for many Canadians from coast to coast.

You are also well versed, I'm sure, in some of the challenges in communities that live under conditions of vulnerability, such as first nations populations or low-income communities. In those communities you would see even more severe consequences. It is very common for nurses to see the same patients readmitted time and time again for the same simple health conditions that could be very easily managed by proper filling and proper compliance with simple generic prescriptions.

• (0935)

**Ms. Tracey Ramsey:** Thank you for that.

My second question is for Mr. Elliott.

You talk about this policy space. For us as parliamentarians, this is incredibly important if we're actually going to improve public health and advocate for public safety. Eventually, I would love to see a

pharmacare program happen. That public space is going to be limited under these trade agreements, and certainly under the TPP.

At the end of your presentation, you started talking about how it will lock us into certain things. One of the things you mentioned was linkage regulations. Could you expand on some of those things that we'd be locked into?

**Mr. Richard Elliott:** Certainly. Thank you for the question. There are others from the industry here, I think, who can also speak to direct experience of how those things operate in practice, those linkage regulations.

The existing notice of compliance regulations under the Food and Drugs Act allow for an originator pharmaceutical company to file what's called a notice of allegation, alleging that a generic manufacturer that is seeking marketing approval of its generic equivalent version of an originator drug will infringe its patent. The automatic effect of filing that notice of allegation is that an injunction is issued against the federal health minister preventing the health minister from giving marketing approval to that generic product for up to 24 months. So merely by filing an allegation, you can buy yourself up to two years of additional market monopoly as an originator manufacturer.

You may lose, at the end of the day, with your claim that your patent would be infringed, but of course during that time, you've made a significant amount of extra money, so there's obviously an incentive to game the system. That system is one that Canada and the U.S. have, but to the best of my knowledge, no other industrialized countries have. It's the system that the Supreme Court of Canada has described as draconian; that is the Supreme Court's word, not mine.

There's a good example of how we're basically making the health regulator, Health Canada, which is supposed to be looking at the quality, safety, and efficacy of medicines, into patent police. We're using one system to try to enforce claims of patent validity, which are sometimes in the end shown to be overbroad. There is an example of regulatory chill that already exists in our current legislation. It's the sort of thing that a number of other TPP countries would now have to introduce under the TPP, which is not particularly helpful. TPP would help to lock in that kind of mechanism.

**The Chair:** Thank you. Your time is up, Ms. Ramsey.

We're going to move to the Liberals and Mr. Peterson for five minutes.

Go ahead, sir.

**Mr. Kyle Peterson (Newmarket—Aurora, Lib.):** Thank you, everyone, for your very informative presentations, and thank you for taking the time to be with us today.

I have a couple of questions. I'm going to start with Innovative Medicines Canada.

In your opinion, what would be the impact on Canadian pharmaceuticals' ability to compete in this market if the TPP were ratified without Canada at the table?

**Mr. Declan Hamill:** Well, it's an interesting question. Thank you for your question.

In terms of the ability to compete internationally, I think you would need to be linked not just to the IP provisions but to the symbol that might send internationally. At this juncture, unless the TPP does not move forward for reasons beyond Canada, I have a hard time seeing the agreement not including Canada. I think it would be difficult to see that that would be in Canada's national interests overall.

With respect to the IP provisions, as we've already discussed, there really aren't a lot of differences in terms of IP provisions. In fact, they're somewhat more lax and less stringent than those which have already been negotiated with the European Union in the context of CETA. It's sort of a multivariable question. If CETA moved forward and the TPP didn't move forward, if the opposite occurred.... That said, the strengthening of the IP provisions is really being driven by the treaty with the European Union, not by the TPP.

The TPP does have one or two interesting aspects which are not found in CETA. There is, for example, a provision relating to patent office delays. These are delays where the Canadian Intellectual Property Office takes too long, an unreasonable delay, to process a patent. That delay standard is set to five years. Right now it takes about 19 months, so it's more a question of principle than an actual practical effect.

Overall, what drives the changes in terms of the IP environment which will require, as Mr. Keon mentioned, some very complicated negotiations, and the devil really is in the detail on implementation, is CETA as opposed to the TPP in Canada.

• (0940)

**Mr. Kyle Peterson:** Thank you.

I have a question for Mr. Keon.

I appreciate this, but you highlighted the difference between cost and price. I'm just going to make sure I'm clear on what that distinction is. The cost is the cost of the production of the product and the price is what the consumer pays, right? Is that the distinction you're trying to make?

**Mr. Jim Keon:** I meant the cost to payers, for example, provincial governments. For example, the cost of Lipitor, a brand-name product, is about \$2.20 a tablet. When the generic comes on, it's down to around 38¢. You can now pay for about five prescriptions for the price of one, so the costs have come down. The price of Lipitor itself may still be the same \$2.20, but the costs to the program are either reduced with generics, or go up because generics aren't available.

**Mr. Kyle Peterson:** Thank you for clarifying that. I wasn't quite clear on what that distinction was, so I appreciate that.

You mentioned that your organization and your members invest heavily in R and D. Do you have that as a percentage of your sales?

**Mr. Jim Keon:** Yes, we report on that.

Our companies do not report to the PMPRB, the Patented Medicine Prices Review Board, as the patent drug companies do, but it's in the range of about 12% to 14% of our revenue. The reason for that and why it's actually higher than the patent holding companies is that a lot of the development is actually done in Canada. There are large manufacturers, like Apotex and Pharmascience, that are

Canadian-based companies. Apotex has been the largest spender on research and development in pharmaceuticals for many years.

**Mr. Kyle Peterson:** That leads to my next question.

In your opinion, what impact would our participation in the TPP have on that R and D investment here in Canada?

**Mr. Jim Keon:** Again, I think I'll come back to the comments others have made. It's CETA and the TPP in combination.

We were very concerned about the patent extension, that the two years would mean that development and manufacturing in Canada would put you behind the curve, that you're not going to be able to develop it as early as possible. An important element for us in that patent extension is that there will be an export clause, meaning companies.... Even though you're not going to be able to sell it in Canada for two more years and drug costs will stay high in Canada, you would be able to manufacture it for export to countries where patents have expired.

That's an important element for us in CETA and in the TPP.

**Mr. Kyle Peterson:** Thank you.

**The Chair:** That pretty well wraps it up, and thank you.

That ends the first round. Before we start the second round, I'll just remind everybody, if you're not fully bilingual, put your headphones on, because questions or answers could come in both languages at any time.

We're going to move to the second round.

The Liberals will start off for five minutes. We have Madame Lapointe.

[*Translation*]

**Ms. Linda Lapointe (Rivière-des-Mille-Îles, Lib.):** Thank you, Mr. Chair.

Welcome to the witnesses appearing before us today. I hope you understand me because I will be speaking in French.

Mr. Labonté, I want to continue talking about the issue raised by my colleague earlier.

If Canada doesn't ratify the TPP, and Mexico and the United States do, what do you think will happen to the price of medications in Canada?

[*English*]

**Mr. Ronald Labonté:** I will have to leave that to other people to try to answer.

Looking at the pharmaceutical industry is not the major focus of the research work that I undertake. However, I would point out a few things around the issues that have been discussed around intellectual property rights and pharmaceuticals. One of them is that the original TRIPS agreement, with its 20-year term, was actually designed to take into account regulatory delays. By putting in patent term extensions, that's a kind of new provision that goes over and above what had already been anticipated as being a sufficiently long period of time of patent protection.

My major concern is less to do about how it's going to affect us if Canada doesn't ratify. I'm concerned that if Canada does ratify, it goes back to more questions about how we extend our public health insurance programs. We've talked about the necessity of trying to create some sort of pharmacare. My concerns about pharmacare would be less about what the drug patent legislation or the chapter in the TPP provides, and more about what the chapter in ISDS provides. That would leave us vulnerable if we extended into a public monopoly program to cover the costs of pharmaceuticals, or it could be dental care, eye care, home care. If we negotiated that in collaboration with the different provinces, we could be vulnerable to an investor-state suit because of how we foreclose the potential of foreign-invested private health insurance in that market.

● (0945)

[Translation]

**Ms. Linda Lapointe:** Thank you very much.

I will now address the question I asked earlier to Mr. Fleming or Mr. Hamill.

If Canada doesn't ratify the agreement, and Mexico and the United States do, how will it affect the prices and investments of companies that research and develop medications?

[English]

**Mr. Mark Fleming:** Thank you very much for the question.

First of all, Canada operates in a very highly controlled price environment for pharmaceuticals. There are multiple layers of bureaucracy between an innovation and that medicine's getting to a patient through a payer. Included in those layers are the Patented Medicine Prices Review Board, which sets the non-excessive price for medicines. A medicine then moves through a health technology assessment agency, for example the common drug review here in Ottawa, where price and value are considered. From there, it moves on to the pan-Canadian Pharmaceutical Alliance or pan-Canadian Pricing Alliance, where a reimbursable or an affordable price is negotiated, and finally makes its way to the payers at the provincial level, before an agreement is signed. Before any of our medicines reach Canadians, the value and the price of that medicine.... They have been proven to be valuable and effective for Canadians and at an affordable price.

Second, what I would say on research and development.... I would just add a caution about making policy decisions based on the Patented Medicine Prices Review Board report that comes out annually. It is a relatively blunt tool based on SR and ED, scientific research and experimental development, which was very valid back in the 1990s when it was set up. It is not valid in measuring full R and D investment today. Regarding my company, specifically, in the last two years, the PMPRB reports us investing \$120 million in Canada, but the reality is that we have invested \$1 billion in Canada. There is an \$880-million gap in life sciences investment. I think it is very important to look at all the facts before we make policy decisions on access to medicines in Canada.

[Translation]

**Ms. Linda Lapointe:** Thank you.

Could this result in research and development being conducted in Asian TPP countries? Do you think it would come to that?

[English]

**Mr. Mark Fleming:** I think the decisions around life sciences and research and development investment are multifactorial. They do not involve just intellectual property; they involve a number of other components. Perhaps the biggest and most important is the quality of science and scientists. Canada has a leading edge on that front. Many of our investments coming into Canada have been based on the wonderful science and scientists that exist in the country, the people who are on the front lines making discoveries and changing people's lives, as opposed to the critics who find the best opportunities to criticize.

**The Chair:** Thank you, Mr. Fleming.

There are only 15 seconds, and Mr. Prouse wanted to jump in there. You can make a quick comment, and then we can move on.

**Mr. Dennis Prouse:** I will be very quick, Mr. Chair.

Our large members are global. They will tell you that the most competitive aspect of their business is the internal debates about where investment will go, whether it is to Canada, to the U.S., to Europe, or to Southeast Asia. That is incredibly competitive. I can't imagine how difficult their job would become for Canada if Canada was excluded from the TPP, yet the United States was in. I think that is where that investment would then go.

**The Chair:** Thank you, sir.

We are now going to move over to the Conservatives for five minutes.

Mr. Van Kesteren, you have the floor.

**Mr. Dave Van Kesteren (Chatham-Kent—Leamington, CPC):** Thank you, Mr. Chair.

Good morning, everybody. Thank you for coming here.

I want to get some perspective here. I am going to direct my questions, and they are very short questions, to both drug organizations.

First of all, correct me if I don't have this right. The pharmaceuticals, in essence, develop drugs that haven't been developed and that cause relief or sometimes cure diseases that plague humankind. That is the main thrust of your research. The generics, in essence.... Once the patent is up, you can break down that drug and create a drug that is similar—it can't be the same—to the pharmaceutical, and then you can sell that drug. Do I have that right? Is that pretty much the gist of both industries? Is that right, Mr. Keon?

● (0950)

**Mr. Jim Keon:** The generics develop competing products that Health Canada declares to be bioequivalent, so they are actually equivalent to the brand-name product. The value we bring is what we call headroom. You can now buy and pay for medications at a much lower cost and spend the money elsewhere in the health care system.

**Mr. Dave Van Kesteren:** In essence, you have the right to copy—not to copy, but to take their research—

**Mr. Jim Keon:** Develop our own products....

**Mr. Dave Van Kesteren:** —and apply it, and the end result is a cheaper product.

**Mr. Jim Keon:** That is correct, after patents expire or are found to be invalid, yes.

**Mr. Dave Van Kesteren:** Yes.

I suffer from migraines. Years ago, there wasn't much relief for that. I was thankful when Tylenol and companies like that first started coming in with drugs. I'm also thankful that today I can go to the drugstore and buy those generic ones.

In essence, what we experience as we move forward in the drug industry is that new drugs are created. You're going to get your investment back, but after a period of time, you can jump in and you can offer. I simply wanted to make sure that we have that perspective in order.

Do you ever get sued, Mr. Keon? I know the pharmaceuticals have had some experiences with drugs in the past that haven't worked out very well. Is that as big a concern as for the pharmaceuticals?

**Mr. Jim Keon:** Our member companies are in litigation all the time over patent issues.

**Mr. Dave Van Kesteren:** Right. But not so much.... I'm thinking of—

**Mr. Jim Keon:** Do you mean consumer concerns?

**Mr. Dave Van Kesteren:** Yes. If you watch American television, you can always jump on the bandwagon of some drug that has caused issues.

**Mr. Jim Keon:** Typically, what happens is generic products are coming on the market 10, 15, or more years after a new medication. Typically, if there have been problems with the medication, that generally has been brought out.

I'm not aware of any case where someone has been sued for getting a generic as opposed to a brand, or anything like that.

**Mr. Dave Van Kesteren:** And the pharmaceuticals, have you ever been sued for some drugs that didn't work out as well as people had hoped?

**Mr. Mark Fleming:** It certainly is part of life. It's part of the dialogue between the generic industry and the innovator industry. Generally, there are resolutions that are reached over time.

It's quite clear that the generic industry brings tremendous value to the health care system. They help long-term affordability. Our focus is really on the innovations. For example, in the past 20 years, 40% of the increase of Canadians' life expectancy has been based on innovative medicines. In—

**Mr. Dave Van Kesteren:** I'm sorry, I don't have much time.

Would it be safe to say that agreements like the TPP and any other free trade agreement give you a further ability to do more research and make more discoveries to prolong our life expectancy and to cure some now incurable diseases? Is that a pretty safe assumption?

**Mr. Mark Fleming:** Certainly, the agreements that have helped to level the playing field on intellectual property on a global perspective allow Canada to compete for global research and development dollars. Our company, J&J, invests \$8 billion globally. On the heels of CETA, we have been successful in attracting significant investment to this country.

**Mr. Dave Van Kesteren:** I have a really quick question, Ms. Pullen.

What is the major cost increase in health care? Is it drugs or is it physician costs, nursing costs, or maybe bricks and mortar? What's the major cost?

**Dr. Carolyn Pullen:** If you look at the most recent report, the 2015 report from CIHI, the top three costs that are increasing steadily year over year are hospitals, physicians, and drugs.

**Mr. Dave Van Kesteren:** In that order?

● (0955)

**Dr. Carolyn Pullen:** I don't remember specifically.

**Mr. Dave Van Kesteren:** Maybe you could get that, too. I appreciate your concerns about pharmaceuticals, but I think we should also put as much focus on the other costs as well.

Maybe you could get that information back to us.

**Dr. Carolyn Pullen:** Yes.

I would add that the three combined account for over 60% of health care expenditures in Canada each year, but I'm afraid I can't give you the specific breakdown.

**The Chair:** I'll pick up on that point. Panellists, if you have a point to make and you didn't get it across today, we'll welcome anything more you can present to us and we'll enter it into our report.

We'll now move back to the Liberals. Ms. Ludwig, you have the floor for five minutes.

**Ms. Karen Ludwig (New Brunswick Southwest, Lib.):** Thank you, Mr. Chair.

Thank you for the excellent presentations.

My first question is for Madam Pullen regarding NCLEX. You mentioned that it's an American-based exam system that doesn't fairly or adequately measure the competencies needed for the Canadian health care environment.

Regardless of whether the TPP is ratified or not, should the NCLEX as a measurement be reviewed?

**Dr. Carolyn Pullen:** Both the implementation of NCLEX in Canada and the reliability and validity of NCLEX in testing nursing competencies relevant in Canada are questionable.

What is unclear right now is whether or not the Canadian regulators will find that to be problematic enough to make a decision to revert to a Canadian entry-to-practice system. I can't say for sure whether or not that decision will be taken in the future, but our concern is that there is enough evidence that this is an avenue worth exploring and the TPP could be a barrier to reversing a decision taken across regulators in Canada to having a made-in-Canada solution.

**Ms. Karen Ludwig:** Thank you.

My second question is for you as well.

Could you please explain the social determinants of health and how they impact on the quality of life and health outcomes and how the social determinants of health may influence the use or the application of drugs?

**Dr. Carolyn Pullen:** The determinants of health are multivariate. They are related to physical health, genetics, the environment, and other social factors such as housing, income, employment, education, etc. To say that the cost of pharmaceuticals, as an example relevant to this conversation, is the only or the most important determinant of health would be giving undue weight to that particular dimension of health.

However, where we have the greatest challenge is with the TPP, and you look at all the determinants of health and pharmaceuticals as a part of that. They play a very important role in helping people maintain health, all other determinants of health being equal. To introduce additional layers of barriers to that one mechanism for maintaining health or managing chronic disease just makes a very important piece of the health of Canadians that much more challenging. I guess that's the challenge that this committee has to weigh.

I have no doubt that there are business benefits for agriculture, for the pharmaceutical industry, and for the auto industry with this trade agreement, but whether there are intended or unintended consequences that affect other sectors and more Canadians than just those involved in those sectors is really the challenge that you have to weigh. Do the benefits for the few outweigh the benefits for the many? The Canadian Nurses Association would stand strongly on the side that this agreement is balanced against the benefits for all Canadians.

**Ms. Karen Ludwig:** Thank you.

If you were presenting before the health committee, would you make recommendations in terms of policy for looking at the social determinants of health outcomes? My daughter is a fourth year nursing student, and so I've read many of the papers and edited most of them, but looking at the social determinants, how would you present to the health committee in terms of making improvements for policy, changes to policy for improvements to health that may prevent the use of drugs in the future?

**The Chair:** You might not have noticed, but Mr. Ruckert also wants to make a few comments. Could you make it quick so then he can follow?

**Dr. Carolyn Pullen:** Actually, I'd like to process your question, so I'll let him make his comments first.

• (1000)

**Mr. Arne Ruckert (Senior Research Associate, Globalization and Health Research Unit, University of Ottawa, Canada Research Chairs Program):** I just want to highlight that we actually did look at some of the social determinants of health pathways that connect the TPP to population health results in Canada. We particularly looked at income and employment as two central social determinants of health. Of course, as you are well aware, most of the econometric studies have not found a significant economic impact. They have found pretty much in the realm of zero or minus 0.2% to plus 0.2% as an impact, which is of course negligible.

At the same time, though, employment impacts have been found to be negative. That's a very important aspect of the health impacts because employment is a central determinant of health. The TPP will lead to approximately 60,000 lost jobs in Canada, according to the Tufts University study, and various other studies also found negative employment impacts.

There are concerns about how actually, through these social determinants of health pathways, the population could also be undermined through the TPP.

**Ms. Karen Ludwig:** Thank you.

**The Chair:** Thank you, and that's your time, Ms. Ludwig.

We're going to move to the Conservatives now. Mr. Shipley, you have five minutes.

Go ahead, sir.

**Mr. Bev Shipley:** Thank you, Mr. Chair.

Thank you, witnesses.

Mr. Fleming, you mentioned the regime to set and approve the price of drugs. Actually, it likely isn't what most Canadians would think, that there's actually a regime. When you do the research and development beyond the amount to develop the product how does that...? Can you just help me with that?

Then I want to go to Mr. Keon to see how they develop it for generic drugs. Just run down that again for clarification. Do you actually establish it or is it a regime that helps to establish the price of the drugs, and what influence do you have as a manufacturer on that final decision?

**Mr. Mark Fleming:** Thank you.

Medicine pricing is a global decision by our organizations. We bring innovative medicines to 160 countries around the world, so we need to consider global issues when it comes to medicine pricing.

Here in Canada the pricing of medicines is significantly controlled, and has been since the early 1990s. The Patented Medicine Prices Review Board here in Ottawa is a federal agency operating under legislation that uses very specific and controlled rules to set prices. They compare Canadian prices versus a basket of seven other international countries, European countries and the United States.

From that point the medicine goes to a health technology assessment agency, primarily under the common drug review. There's a different body in Quebec called INESSS. There, what they are looking at is value for money. They are determining whether the medicine will bring value to the health care system compared to what is currently available to treat illness. Finally, or almost finally, from there it moves on to a provincial process. All 10 provinces are involved. That's called the pan-Canadian Pharmaceutical Alliance where they will negotiate significant price discounts. In fact, in the past 24 months the pCPA has saved \$500 million for the Canadian health care system.

**Mr. Bev Shipley:** Is it somewhat similar, Mr. Keon?

**Mr. Jim Keon:** No, the generic pharmaceutical companies are not subject directly to the Patented Medicine Prices Review Board. However, we have negotiated over the last number of years with the pan-Canadian Pharmaceutical Alliance, which is now a very forceful organization representing all the provinces.

Our prices are tied to the price of the equivalent brand, and they're set at a per cent of that. For example, on the top 18 selling generics, the price is capped at 18%. If you want to go on the formularies, you can't sell it for any more than that. The provinces control our prices.

**Mr. Bev Shipley:** Thank you.

Mr. Prouse, we've continually heard that these negotiations are all done in secret, which is quite untrue. Can you tell me not only with the organizations that you represent but the commodity organizations that rely on your organization to become effective and efficient in the production of this, would you say that they were or were not involved in terms of having access to the discussions through the commodity organizations?

**Mr. Dennis Prouse:** They were all extremely involved. You're talking about groups like the Canadian Agri-Food Trade Alliance, CAFTA, the Canola Council of Canada, the Canadian Canola Growers Association, the Grain Growers of Canada, the Canadian Horticultural Council, Canada Grains Council, and no doubt I'm missing a few, but all of these groups were directly involved. Many of them were on the same trips and were probably drinking the same coffee that Jody was drinking when they were in all those same meetings.

• (1005)

**Mr. Bev Shipley:** Okay, thank you.

What we're talking about is basically health care. Many don't relate agriculture to the significance of health care and being able to take the science and the innovative part that we have in agriculture to produce actually some of the safest, if not the best and safest food in the world. If we do not get involved and ratify the TPP, does that put us behind the eight ball in terms of being effective and efficient with regard to our research to be able to give our agriculture community... Quite honestly, folks, I think we all understand that one of the most, if not the most, significant large industries is agriculture, because it is the one that all foundations of trade agreements are built on because everybody wants safe, secure food. That's what it's about.

Dennis, I'm wondering—

**The Chair:** Mr. Shipley, your time is up.

**Mr. Bev Shipley:** I know, but can we get an answer?

**The Chair:** You're going to have to wait. It's not like the agriculture committee. We run a tight ship.

**Some hon. members:** Oh, oh!

**Mr. Bev Shipley:** I'll tell Pat that.

**The Chair:** You might throw that question to one of your colleagues for the next round, but we're going to move to the NDP now.

For three minutes, Ms. Ramsey.

**Ms. Tracey Ramsey:** Thank you very much.

Farmers are linked to what we're talking about. Farmers in my riding can't afford their medication, so this is an issue that is very important to farming communities. When we look at the cost of drugs, it's upwards of \$24,000 a year for something like Enbrel for someone who has rheumatoid arthritis, and that can be a farmer too.

My question is for Mr. Labonté.

You mentioned something in your presentation about a carve-out and it was around tobacco labelling. I wonder if you could speak to us about that particular carve-out and its implications on public health and why you think it's significant that it is a piece of what was actually negotiated.

**Mr. Ronald Labonté:** Okay, and thank you.

Well, it's not a carve-out in a legal sense. It's an exclusion, and it's a voluntary exclusion. If the TPP is ratified and enters into force, countries can voluntarily exclude all of their tobacco control measures from an investor-state dispute. That's written into the ISDS, so they can do that voluntarily. But it doesn't prevent a state-to-state dispute settlement or a panel from being created. If there's a tobacco transnational that sort of lobbies one of the TPP countries somewhere and says it's going to object to a tobacco control measure, let's say in Canada, maybe perhaps with plain packaging, it could still initiate a dispute under the state-to-state dispute provisions of the TPP. So it's not a full carve-out.

As well, tobacco transnationals can shop around and try to find a different investment treaty to which Canada might be a party and could still try to launch a dispute under that investment treaty. The TPP does not exclude potential suits. I think the significance of it is a recognition when the TPP was being negotiated—highlighted because of the problems that were happening with Australia's plain packaging at the time and with Uruguay with some of the challenges it's been facing—that these investor-state dispute chapters actually oppose challenges or regulatory chill around tobacco control measures.

Our concern extends beyond that, because you have obesogenic food items, alcohol, sugar, and other globally traded commodities that we know increasingly are posing long-term health risks. Our question was that, if it was important enough to try to allow or create and send a signal about a tobacco control exemption under investor-state dispute, why was that not extended to all non-discriminatory public health measures that were intended to essentially deal with the problems we face now, but also to anticipate the problems we're going to be facing down the road?

**The Chair:** Thank you, Mr. Labonté.

Your time is up, Ms. Ramsey.

We're going to move over to the Liberals.

Mr. Fonseca, you're up for five minutes. Go ahead, sir.

**Mr. Peter Fonseca (Mississauga East—Cooksville, Lib.):** Thank you, Mr. Chair.

I want to ask Mr. Prouse and Ms. Cox about these coffee drinking binges, these meetings, these trips you were on, and anybody else who might be involved in those trips, about the TPP and the negotiations.

We've heard criticism that Canada was late to the table. The United States had been there in 2008. These negotiations with some of the other countries in the TPP had started back in 2006, and Canada was one of the last involved, in 2012. Were there some concerns about that? Were there chapters that were closed? Were there parts of the TPP that you could not look at reopening or negotiating and putting your voice on the table?

• (1010)

**Mr. Dennis Prouse:** I'm certainly not aware of any of those concerns. Our members are concerned about all trade agreements. This is one. Obviously, there was a great deal of interest in CETA at the time that CETA was going on, so at any—

**Mr. Peter Fonseca:** I'm talking about the TPP. The U.S. came on in 2008, and we came on in 2012, four years later.

**Mr. Dennis Prouse:** I think our members' biggest concern, and it was pretty focused, was on making sure there was a science-based regulatory part of this. I think the fall of the tariffs was one part. I think our focus was pretty singular, and we felt it was met, notwithstanding when we may or may not have come in.

**Mr. Peter Fonseca:** Go ahead, Ms. Cox.

**Ms. Jody Cox:** I would say that when Canada entered the negotiations, certainly from our perspective, I believe there were certain provisions that may have been tabled by different parties, but they hadn't actually been substantially negotiated, or the countries hadn't landed anywhere on those particular provisions.

In terms of the areas of focus for our industry, I think everything was available for discussion for Canadian negotiators—at least that was my understanding—and also for other countries that were joining at the same time, Mexico, for one.

**Mr. Peter Fonseca:** From the brand side, can you remember the brand drugs? From your global head offices, were you already hearing about the TPP? Were you getting wind of it, and what were

you hearing prior to being called and asked for your opinion on it from the Government of Canada at the time?

**Mr. Mark Fleming:** Certainly, our organization watches and looks closely at all international trade agreements, as they may have an impact on our business, whether it's the movement of goods or whether it's related to research and development or intellectual property. Our company was around the table and closely observing the TPP as it developed, as were many of our sister companies that we compete with.

I would say, as we watched the intellectual property chapter, certainly from a Canadian perspective, our observation was that it was essentially piggybacking on CETA, so that there really was no significant or dramatic change in the TPP from what we were already seeing in CETA. That enabled us to continue our support of CETA.

**Mr. Peter Fonseca:** Most Canadians that I speak to in my riding, in Mississauga, and we were just in Winnipeg speaking to some people on the street.... What they want to know about the TPP, or the little that they do know is that it's going to bring us some good, paying jobs to Canada. Is this going to make us more competitive? What will it do for our trade? Most of the witnesses we've heard from talk about pure trade in terms of imports and exports. This is a very different type of meeting that we're having here today, talking mostly about IP, and how competitive you would be.

Going to the jobs, on the brand side, how many direct jobs do you have here in Canada?

**Mr. Mark Fleming:** Our employment is 15,000, and indirect is up to 31,000 employees in Canada. Perhaps I could just add to it, because I think I understand where your question is going.

In addition to the research and development we do, we have a major manufacturing plant in Guelph that manufactures 2.1 billion tablets on an annual basis that we export to the Middle East, to Africa, and as well to the U.S. There is the potential of an opportunity from an enhanced international trade, enhanced jobs, etc., from that Guelph plant to countries in the TPP region.

**The Chair:** If I may, I think Mr. Keon wants to....

**Mr. Peter Fonseca:** Mr. Keon, yes.

**Mr. Jim Keon:** Just briefly, one of the problems that joining late made perhaps, is that the focus on pharmaceuticals is all about intellectual property: let's increase intellectual property around the world. For a generic pharmaceutical industry in Canada and globally, that has a lot of problems in terms of when we can enter the market.

What we would like to see more focus on in the future is regulatory harmonization, trying to make it available so that when you develop a drug for Canada you can sell it elsewhere without having to redo tests and increase costs.

That's something I'd like to table with the committee going forward.

• (1015)

**The Chair:** Thank you, sir.

That wraps up the Liberal time and that round. We have a half round, I guess, and we're going to move over to the Conservatives for five minutes.

Go ahead, Mr. Ritz.

**Hon. Gerry Ritz:** Thank you, Mr. Chair.

I would just like to build on that point you were making, Jim. We have begun that process with our major trading partner, the U.S.—beyond the border and regulatory co-operation—and a lot of that discussion also happened with CETA, and could then spill over into the TPP as well. There's nothing stopping businesses within the TPP envelope or the CETA envelope from talking about this regulatory co-operation, recognizing each other's science. Rather than reinventing the wheel, you just add air and go again. That's an excellent point to make, and something that we should highlight in our report going forward.

One of the other issues that has come up, that seems to be quite a sore point with certain groups, but not with others, is labour mobility. I think it was Mr. Fleming who made the point that you have 15,000 people, 31,000 overall.

Is there the ability, or do you see the ability to bring in expertise from around the world for a specified period of time, a month or two or three, to do certain things, and then also export that expertise to other countries within the trade zones?

**Mr. Declan Hamill:** First of all, I have to say I'm not an expert on labour mobility. That said, we have had a number of member companies who have spoken positively about the labour mobility provisions particular in the CETA, because there are a number of member companies that are based in the European Union, so, yes, it does help when Canadians can move to Europe more easily, and vice versa. There's no question that it is helpful.

**Hon. Gerry Ritz:** Okay. I know in the agricultural sector, Dennis, that's something that seems to be important as well.

**Mr. Dennis Prouse:** Oh, no question. Not so much directly for us, but certainly for the grower groups in the GrowCanada partnership, that is an issue with which they're always wrestling.

**Hon. Gerry Ritz:** There's a tremendous amount of mentorship required. In a lot of the growing markets, Vietnam, Malaysia and so on, they're looking for Canada to come in with certain expertise on land use and different things like that, so it's a matter of being able to do that, and of course under the TPP we can.

**Mr. Dennis Prouse:** Every time I turn around one of our member companies is making a trip to those kinds of emerging markets that you're discussing, absolutely.

**Hon. Gerry Ritz:** Yes.

On the science side, it's not just about tariffs. It's great to see tariff walls come down. It gives you that footprint to get in there. Then it comes down to agreements on maximum residue levels and low-level presence, MRLs and LLPs. Those are all done under Codex internationally, but Codex is so far behind the eight ball. Do you see an opportunity here for like-minded countries within a trading bloc to make changes, agree on the science on MRLs and LLPs?

**Mr. Dennis Prouse:** That's certainly what we're hoping for. We talk about a coalition of the willing, if you will, made up of the major

exporting countries, which all have a science-based regulatory system. To your point earlier, we don't see any reason that countries that have a science-based regulatory system can't come to agreements on these very basic matters. It facilitates trade greatly. Nothing is a bigger barrier to trade than those non-tariff barriers that we run into.

**Hon. Gerry Ritz:** Predictability and stability make trade work. That's to Jim's point about science harmonization.

I turn it over to my colleague, Mr. Van Kesteren, if I have any time left.

**The Chair:** Go ahead. You have two minutes.

**Mr. Dave Van Kesteren:** Dr. Pullen, we didn't finish off the point I was trying to make. We all know that health care costs are rising significantly. You would agree the rise in cost is not just for pharmaceuticals; it's nurses, doctors, personnel in the hospital, the buildings. It's everything. I think that's a point we all have to recognize, as well.

I just want a clarification. You said earlier that you were concerned about the cost for first nations. Was that correct? Did I catch that? I just caught it. I wanted to make sure—

**Dr. Carolyn Pullen:** The linkage there is that the federal government is the provider of health services, including medications, to first nations and Inuit health in Canada. They are both a funder and a provider, so they're going to be hit doubly by any changes to the cost of drugs in Canada.

**Mr. Dave Van Kesteren:** The federal government. We're aware that the first nations costs are 100% covered by the federal government.

**Dr. Carolyn Pullen:** Yes.

**Mr. Dave Van Kesteren:** That's all I wanted to know.

Thank you.

**The Chair:** Thank you.

We're going to go over to the Liberals. You have a bit of a split time for five minutes.

Go ahead, gentlemen.

**Mr. Sukh Dhaliwal:** Thank you, Mr. Chair.

To the panel members, I'd like your thoughts about a fair scenario that will balance a pharmaceutical company's ability to develop a drug without rushing, but the generic drugs need to enter the market and compete.

Mr. Elliot.

•(1020)

**Mr. Richard Elliott:** Thank you.

I think we can debate a bit what would constitute a fair scenario. I think it's fair to say that all WTO members agreed on the TRIPS agreement, the agreement on intellectual property rights, back in 1994.

All of the discussion now globally, except in the context of these particular trade agreements, is about the need to preserve the balance that was struck in the TRIPS agreement, whether the balance that was struck there was the right one, or whether we need more flexibility for countries because we're not getting either the innovation that we need in the pharmaceutical sector to address global health needs or the access to those products.

Rather than sign agreements that restrict that flexibility further, the discussion is about ensuring that flexibility is preserved where it exists, and that balance was struck at the WTO, and possibly it will increase. The TPP seems to be going exactly the wrong way. There's no need for us to move off of what was already agreed in the TRIPS agreement at the WTO. Some might say it's not a fair balance, but it's certainly a fairer balance than the TPP would strike.

**Mr. Sukh Dhaliwal:** Would anyone else like to comment?

Yes, please, Mr. Hamill.

**Mr. Declan Hamill:** I'd like to make the observation that when member companies of our association are competing for R and D, and trying to promote Canada as a destination, they're not competing against the lowest common denominator. They're competing against other developed nations, most of whom have TRIPS plus IP, and have had TRIPS plus IP for many decades.

The level playing field is not with China or India. The level playing field is with the European Union, Japan, the United States, and other developed countries because that's the competition for R and D investment.

**Mr. Sukh Dhaliwal:** Mr. Keon.

**Mr. Jim Keon:** One of the things about the balance between the pharmaceutical patent protection and generic entry is not just the term of patent protection; it's also the complexity. We have a complex litigation system in Canada. Mr. Elliott mentioned it earlier about patent linkage. We're blocked from going into market simply by someone claiming we're infringing a patent, which forces enormous amounts of litigation in Canada if you want generics to come on the market. It's expensive and complex, and with the pricing regime that I mentioned earlier, the price is coming down. One of the problems that we have now that doesn't get a lot of attention is, what the incentives are to bring generics to market.

If you're going to market and you're selling it at 18¢, but you're potentially liable for a patent infringement at a dollar, and you start selling a number of these prescriptions, you're liable for lots of potential liability. We need to have a simpler system.

One of the problems with the TPP is that it is imposing this system on a lot of other countries, particularly developing countries, which probably don't have the infrastructure to handle it.

As people talk about access to medicines, it's not just patent terms; I think it's the complexity of the system. In the TPP, we're importing further complexity into that pharmaceutical patent litigation system.

**Mr. Sukh Dhaliwal:** Mr. Hamill, you mentioned India and China. It's my understanding that most of the generic drugs are produced in India, and for the nations that we are getting into the TPP with, that is not going to be an issue, countries like India. Do you agree with that?

**Mr. Declan Hamill:** Well, I think Mr. Keon and Ms. Cox would probably take issue with most generic drugs being produced in India, since they produce generic drugs in Canada. It is true there are economies of scale which are to be had in developing nations, so if most product ingredients that are the foundation of pharmaceutical products are already made in India and China and labour costs are lower there, you will see a flow of generic manufacturing—you already have seen a flow of generic manufacturing—to those markets. There's that, combined with the increasing size of the market, which can't be denied either, the growing middle class in India, for example.

That said, as I said before, we're not competing...we can't compete on that basis with those countries. We're competing with the European Union, the U.S., Japan, and other developed nations, on the innovative side of things.

**Mr. Sukh Dhaliwal:** Okay, thank you.

**The Chair:** Time to wrap up there, boys, it's all done.

We're going to have one more MP, and that's Madam Ramsey, for three minutes.

Go ahead, and that will wrap up our session here.

**Ms. Tracey Ramsey:** Thank you so much. You've given us so much to think about. I think we could go on and on, digging down further.

The interesting thing you're talking about, Mr. Elliott, is that we're actually going to restrict our flexibility, and I think the reason that this is part of CETA and the TPP is that if CETA isn't ratified, then it comes into force in the TPP. There's an assumption that CETA will be ratified, but we don't know that. We're looking at what's happening in the EU.

My question is really simple. Is there a need for Canada to increase the intellectual property protections that are provided to pharmaceutical products?

I'll start with Ms. Cox and go around the table.

● (1025)

**Ms. Jody Cox:** I'll give you a simple answer, no. Mr. Keon might elaborate on that.

**Mr. Jim Keon:** No, we have strong intellectual property protection. I think in trade agreements, as I said earlier, we would like to see more focus on regulatory convergence. That would reduce costs, improve quality and, I think, make medicines much more available in Canada and in developing countries.

**Ms. Tracey Ramsey:** Mr. Elliott.

**Mr. Richard Elliott:** The answer is no.

I think it's worth noting that in the CETA negotiations one of the major areas of concern has been the investment chapter, and that has been one of the major stumbling blocks, particularly in Europe, because of the potential negative consequences of it. I'm not sure why we would want to replicate that in the TPP, especially when we already know, from our own experience under a similar chapter in NAFTA, that it creates the opportunity for pharmaceutical companies to try to challenge our flexibility, in this case, patentability criteria.

**Mr. Dennis Prouse:** There was no change in the TPP for IP on seeds, nor were our members looking for any.

**Mr. Arne Ruckert:** We would also agree with Mr. Elliott that certainly, our answer would be no, and we believe that the WTO agreement adequately protected intellectual property rights.

**Dr. Carolyn Pullen:** We haven't heard any arguments in favour, but I do defer to those who work in the industry.

**Ms. Tracey Ramsey:** Okay.

Mr. Fleming.

**Mr. Mark Fleming:** CETA has provided important IP enhancements that we have been leveraging very successfully. We're putting our money where our mouth is regarding attracting R and D investment to Canada and competing on the global stage for research and development investment.

**Mr. Declan Hamill:** It won't surprise you that there is also a yes column. I would just go back to a point made earlier by CGP on regulatory convergence and harmonization. We agree with that. It's a necessary but but it is not a sufficient condition. You also need to be competitive on IP, but certainly regulatory co-operation, as part of international trade agreements, is something we support, too.

**Ms. Tracey Ramsey:** Something we hear across a lot of industries is that harmonization is a really large issue. Whether we're able to get into these markets really isn't dependent upon some of these shifts, it's that we can't actually harmonize in a way to get into those markets. We certainly hear that repeated over and over across many different sectors.

Yes, Mr. Elliott.

**The Chair:** It will have to be a quick answer.

**Mr. Richard Elliott:** Yes.

I was going to say harmonization can be a good thing, but we shouldn't assume that it is. If you harmonize down to the lowest common denominator and you sacrifice to the public interest, that's not good harmonization. If Jimmy jumps off the bridge, it doesn't mean we should too, right?

**Ms. Tracey Ramsey:** We need to harmonize that.

**The Chair:** Okay. That ends our morning.

Thanks to all the witnesses for coming with very different opinions in different sectors. It was a very fruitful discussion with the MPs. If you have any comments you couldn't get across, or anything else you think of, send it to our committee and we'll put it in our report.

We're going to suspend for three minutes now, because we're going in camera, so I ask everybody but the MPs to leave the room as soon as they can.

Thank you.

*[Proceedings continue in camera]*

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