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**EVIDENCE**

## Tuesday, October 26, 2010

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## Chair

**Mr. David Sweet**

# Standing Committee on Industry, Science and Technology

**Tuesday, October 26, 2010**

● (0830)

[*English*]

**The Chair (Mr. David Sweet (Ancaster—Dundas—Flamborough—Westdale, CPC)):** Good morning, ladies and gentlemen. This is the 40th meeting of the Standing Committee of Industry, Science and Technology. We're studying Bill C-393, an act to amend the Patent Act.

I'd like to let you know that our meetings today are long and complex. We're going to have three one-and-a-half-hour sessions. The witnesses are going to have five minutes for opening statements. I'll introduce them in a second. We're also going to have witnesses, in two of the three segments, by video conference.

Here with us right now, from the Universities Allied for Essential Medicines, is Rachel Kiddell-Monroe. We also have Amir Attaran, who is a Canada research chair of law, population health, and global development policy at the University of Ottawa; and Richard Dearden, who is a partner at Gowlings.

As you can see, the screens are black right now, but our intention is to have, by video conference, from Tallahassee, Florida, Frederick M. Abbott, from the Florida State University College of Law, as well as Joshua Kimani, from the Canadian Medical Institute in Kenya.

We will start with the witnesses here in front of us, and hopefully, by technology, we'll have the others join us before the opening statements of the witnesses who are with us right now.

Mr. Dearden, I think you were the first one here, so you're probably the most ready. I'll let you begin with your opening comments, for five minutes.

**Mr. Richard Dearden (Partner, Gowlings, As an Individual):** Thank you, Mr. Chair and members of the committee, for permitting me to testify about why, in my opinion, Bill C-393 fails to comply with Canada's international treaty obligations.

I am a partner at Gowling Lafleur Henderson. I have practised international trade law for over three decades. You'll find a short biography in tab 1 of my written submissions. Those written submissions, members, explain why Bill C-393 violates the TRIPS agreement and also the carefully negotiated international solution to the access to medicines problem embodied in the WTO's General Council decision of August 2003.

Today I wish to address two points for your consideration, if I could. Firstly, Bill C-393's one-licence regime is not authorized by flexibilities found in the TRIPS agreement. And secondly, TRIPS article 30's limited exceptions provision does not authorize Canada to abrogate its compulsory licence obligations that Canada has agreed to, both in the TRIPS agreement and in the General Council decision.

Now, point one, you'll hear some people argue that you can replace CAMR, Canada's access to medicines regime, through flexibilities available under the TRIPS agreement. The 2001 Doha declaration required members to maintain their commitments in the TRIPS agreement but recognized that there were flexibilities in the TRIPS agreement. And it gave several examples, one of which was compulsory licensing. But the compulsory licensing obligation that existed at the time was only predominantly for the supply of the domestic market, so it didn't solve the problem.

That's why, Mr. Chair and members of the committee, the WTO ministers gave the following instructions to the TRIPS council. And they're found in paragraph 6. That's why you hear of it as the "paragraph 6 system". It reads:

> We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem....

And that expeditious solution, Mr. Chair and members, is what you find in the 2003 General Council decision.

So Canada can only rely on this decision to issue compulsory licences for export if it complies with the conditions in that decision. And in my respectful opinion, CAMR does that and Bill C-393 does not.

I'd also, as a sidebar here, point out to you that my submissions only deal with TRIPS, but NAFTA has an almost identical compulsory licence obligation in article 1709(10). And you should know that Canada and the U.S. entered a memorandum of understanding that suspended the compulsory licence obligations you find in NAFTA article 1709(10)(f), which was identical to the TRIPS compulsory licensing obligation. That suspension is only valid with respect to the compulsory licence issued in accordance with the WTO General Council decision.

So if the Bill C-393 system were allowed, in my respectful submission, it would be violating NAFTA article 1709(10) because it allows for any drug, in unlimited quantities, for an unlimited term, for export to 140 countries. And that is not in accordance with the General Council decision. It would be offside the NAFTA obligations. And Canada, in my opinion, would end up in a dispute settlement panel under NAFTA.

My second point, Mr. Chair, is with respect to an argument that the single-licence regime proposed by Bill C-393 would be authorized by a limited exceptions provision we find in article 30 of TRIPS. Now, let's not forget, Mr. Chair and members of the committee, that the WTO membership rejected TRIPS article 30 as an expeditious solution to the access to medicines problem. But even if article 30 was available to Canada, the burden would be on Canada to demonstrate before a WTO panel that this one-licence regime is a limited exception; does not "unreasonably conflict with normal exploitation of the patent"; and does not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

● (0835)

Canada lost a WTO case involving a Patent Act provision that allowed generic manufacturers to stockpile pharmaceutical drugs for the last six months of a 20-year patent term. We lost that. Canada defended it by arguing that it was okay using the limited exceptions under article 30. The panel rejected that, saying six months was a commercially significant period of time, especially since there were no limits at all on the volume of production allowed or the market destination of such production. So rather than being a limited exception, Mr. Chair, Bill C-393is an unlimited exception because it authorizes a compulsory licence for any drug, in unlimited quantities, for an unlimited duration of time. It does not take into account the legitimate interest of patients who benefit from the incentives that patent protection provides for research and development of life-saving drugs or drugs that improve Canadians' quality of life.

In conclusion, Mr. Chair, what are the proponents of Bill C-393 asking you to do? They're asking you to bypass the WTO and unilaterally renegotiate Canada's compulsory licence obligations through this one licensing system. But what has changed in terms of compliance with our international treaty obligations since the Minister of Industry's 2007 report on the statutory review of CAMR? The only change has been that Canada has accepted the protocol amending the TRIPS agreement that would make the general council decision a permanent amendment. So rather than Canada retreating from CAMR, Canada has in fact further entrenched its commitment to CAMR.

Thank you, Mr. Chair and members.

● (0840)

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

We'll now move to Madam Kiddell-Monroe for five minutes.

[*Translation*]

**Mrs. Rachel Kiddell-Monroe (Chair, Universities Allied for Essential Medicines):** Good morning. Thank you for inviting me to your meeting. I am very happy to be here.

I also want to thank my students from McGill University, who gave me permission to be here today. Another professor is replacing me, and I'd like to thank him as well.

I have worked with human aid organizations, mostly in Asia and through the Doctors Without Borders organization. Memories of Africa still haunt me.

[*English*]

My team took over a project from the French military in 1994 in the dying gasps of the genocide in northwestern Rwanda. We walked into a very fine hospital with fine surgical units, with wards where the patients could be. There was one room where the doors were locked. I asked, "What is behind this door?" I was told those were people I could do nothing for and just to focus on the people I could help. I asked to look behind those doors, and what I saw basically were breathing skeletons. They were people who were dying from HIV/AIDS. At that time, while patients in Canada, Britain, the U.S., and many other developed countries in the world were able to receive life-saving HIV/AIDS treatment, those people did not have access.

I called my headquarters and asked if we could get some medicines for those people: "What we can do? We have to help them." They said they were sorry, but it would cost $12,000 per patient, per year. They said: "These people have a chronic disease. We cannot help them." So we had to sit every night and hold these people's hands. We had to comb their hair and talk to them because we were the last people who were to have any contact with them. We watched those patients die.

I believe it's important to bring that to you people here and to those who say we shouldn't make this an emotional issue. But this is about human lives. This is about people who are dying while people in our countries do not have to die. This is about a situation where people do not have access to essential medicines.

It's not the first time I have appeared before this parliamentary committee in the last seven years, which is how long I have been working on this issue. I first appeared in 2004 before this same committee, urging it to reform Canada's access to medicines regime as was then proposed, because there were fundamental flaws in it. The legislation was passed as it was, and we decided as Médecins Sans Frontières to try to test the legislation, because there was so much goodwill, both in the government, the Prime Minister's Office, and from all parties who voted in favour of the legislation and making this work.

So we decided to try to test it. After four years—four years—we managed to get one drug for a limited number of patients to one country. In those four years, about 40 million people died because they did not have access to essential medicines.

We're not saying that Canada is the solution to the whole crisis, but that Canada has a role to play. Canada is not a panacea, but it has an international commitment that it took in 2003 to try to make the August 30 decision work in Canada. We still have that commitment today. We can do it better, and we should do it better.

I worked with my colleagues inside of MSF, and Cailin Morrison in particular, as well as Richard Elliott from the Canadian HIV/AIDS Legal Network, to try to make this order happen, with all the best intentions and goodwill. We went to many countries through our MSF teams, asking governments to please apply and to use that piece of legislation. When we approached the health ministries, they were all thrilled. They would say: "Wonderful, it's another way maybe we can get drugs for our people at last. We need every single mechanism we can find to treat our patients." We were hopeful. Then when they went to their foreign affairs ministries or to their trade ministries, a block was put on it.

Why was that block put on it? The block was put on it because of the experiences of countries like Thailand, who tried to use flexibilities in their regimes to use compulsory licensing, as Richard Dearden was saying earlier, in domestic situations. When Thailand used a compulsory licence, sanctions immediately came down on them. Abbott, a pharmaceutical company, withdrew drugs and threatened to withdraw other drugs from the Thai market if they didn't change the way they were acting. The U.S. government put Thailand onto the 301 watchlist, as a partner who should not be trusted in matters of intellectual property.

The European Union trade commissioner, Peter Mandelson, sent a letter to the Thai government, threatening them over their use of compulsory licenses and saying they should spend more time negotiating with pharmaceutical companies. They had in fact held over 20 meetings with pharmaceutical companies on this issue to try to get AIDS drugs for the dying Thai population.

Why is the law failing? Some people will refer to market failures, as my colleague on my right will say. Well, I would respectfully submit, the market failures are not an issue for parliamentarians around this table. What you have to do is to make a law that has all the best chances to win, which Bill C-393 has. The market issues are things that should be left to the pharmaceutical companies and the generic companies in trying to make it work.

I would say that references to other forms of fixed-dose combination, which are not same as the fixed-dose combination Apotex produces, will not give fair price comparisons.

● (0845)

Finally, I would like to raise something that has been of great concern to me and many of my colleagues. We've been hearing that there is a move afoot to kill Bill C-393. In the next session, when a vote has to be held on the new sponsor of this private member's bill, there will be people who will prevent it from passing. I would like to submit that this is not a way to democratically deal with the bill, and it would definitely undermine the extremely important work this honourable committee is doing. So I wanted to raise that to your attention, and I do sincerely hope, as a new Canadian citizen, who got her citizenship in March this year, that this is not what Canada would do to this bill.

As a final thing, when I came here to Canada with my family, I had promised the patients I had worked with for over 15 years in Africa and Asia that I would be able to do something here. I believe that Canada is a great country and we have a power to make change.

Thank you.

**The Chair:** Thank you, Madam Kiddell-Monroe.

Now we go to Amir Attaran for five minutes.

**Dr. Amir Attaran (Canada Research Chair, Law, Population Health, and Global Development Policy, University of Ottawa, As an Individual):** Thank you, Mr. Chairman, and good morning.

[*Translation*]

I'm an anglophone, so I'll speak in English, but I would be more than happy to answer your questions in French.

[*English*]

I'm a professor in the faculties of medicine and law and the Canada research chair for population health and global development policy at the University of Ottawa.

I began my research on access to medicines over a decade ago while employed at Harvard, Yale, and Chatham House in London. I've published on the subject in *The Lancet* and in the *Canadian Medical Association Journal*. In full disclosure, I am or have been on the editorial teams of both those medical journals. I've also been unusually privileged to serve on all sides of this debate as a consultant. I have served Médecins Sans Frontières as a consultant at one time and I've served developing country governments such as Brazil and Malawi. I've served drug companies such as Novartis and international organizations like the World Health Organization and the World Bank.

I thank you for calling on me to discuss Bill C-393, and as I sit here I know all of you, all members, all political parties approach this bill with good intentions. This is clear. And you have hopes and prayers that will help the world's poor. This is clear. It is therefore my unhappy job to tell you why I think the bill will probably have zero results for public health and would likely even do harm. Please let me explain.

When CAMR was enacted in 2005, its raison d'être was to make it possible for poor countries to buy cheaper generic medicines manufactured in Canada. To make this possible, CAMR authorized patent overrides of a kind called compulsory licences, and Parliament believed that by overriding patents in cases of acute humanitarian urgency like malaria, like AIDS, poor countries would beat a path to Canada's door for those medicines.

However, as you know, it hasn't worked out that way. Everyone agrees that CAMR has been a one-shot wonder, and only a single country, as Rachel correctly said, Rwanda, bought medicines under CAMR from a Canadian company, Apotex. As Apotex's own spokesperson, Elie Betito, said to the Ottawa *Citizen*, "We will not be doing this again." Everyone agrees, this law is a failure.

Well, how come? In a correct diagnosis, CAMR has failed for economic and not legal reasons. The causes of failure are not in the statute of CAMR, which Bill C-393 could amend, but in reality the causes of failure are in global medicine markets, which no conceivable bill can affect. Rachel's correct about this. I'm sorry to say so, but Parliament simply is powerless to make this law work.

Here's the basic problem: for CAMR to succeed and achieve regular exports of Canadian generic medicines to poor countries, it's necessary for those Canadian generic medicines to be priced competitively compared to other generics on the global market. If Canadian generics cost more than foreign generics, poor countries will buy foreign generics, as well they should: that's how free trade works.

Canadian generics, though, and this is unfortunate, are among the most expensive in the world. And let me share with you some data from the federal government's Patented Medicine Prices Review Board. In 2006 this federal agency compared generic medicine prices in Canada and abroad and it found that compared to Canada generics cost 35% less in America, 51% less in Finland, and a whopping 77% less in New Zealand. Now, I emphasize that these are not industry-sponsored data. They are not activist-sponsored data. They are federal government data of a federal government agency and are trustworthy. What they show is that Canadian generics are among the most expensive in the world, and certainly the most expensive in that study. And as you might guess, overpriced medicines don't sell.

So put yourself in the shoes of an African health minister. Why use CAMR to buy generics from Canada when you can buy generics from America, Europe, India, China, New Zealand, and what have you, for less? This economic reality makes it puzzling why certain AIDS activists insist on supplying the world's poor with Canadian medicines manufactured under CAMR. It's patriotic of them. It's definitely well-meaning of them, I don't wish to take that away; it is well-meaning, but it's also naive.

● (0850)

By selling poor countries more expensive Canadian medicines, the corollary is that fewer patients could be treated on a given budget. It could do harm.

Knowing this, the activists support Bill C-393's amendments to amend the Food and Drugs Act and remove generics produced under CAMR from Health Canada's regulations. That aspect of Bill C-393 is, frankly, terrifying. For activists to champion the deregulation of life and death medicines to save a buck, it is not simply vertiginously irresponsible, it's also medically unethical.

If I may have one minute, I'll wrap up.

In closing, my advice is to forget about Bill C-393 and accept the present reality that including Canada, as elsewhere, there are about 30 countries with such laws. Laws such as CAMR don't work.

This is not to say the House should cease caring about public health in poor countries—far from it. Please maintain your interest, but take the energies, the very good, well-intentioned energies you and others have, that are now absorbed in the sinkhole of CAMR and direct them to reforms of other kinds.

Fix the fact that CIDA is a sclerotic agency. Fix the fact that one-third to one-half of malaria medicines, like I'm holding here, are fakes, are counterfeits in developing countries. They kill children. Stop exporting asbestos. These are things Canadians can do that will save lives. Bill C-393 I don't believe will.

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

**Dr. Amir Attaran:** Thank you for listening to me this morning. I appreciate your efforts on this bill.

**The Chair:** Now we have our two guests by teleconference. Thank you, gentlemen, for taking the time to join us.

I'll go first to Joshua Kimani, who's in Nairobi, Kenya.

Sir, if you could keep your opening remarks to five minutes, that would be appreciated.

**Dr. Joshua Kimani (Canadian Medical Institute in Kenya, As an Individual):** Thank you, Mr. Chair and members of the committee.

I'm Kenyan. I live and work in Kenya, currently with HIV-infected individuals.

Kenya has a population of 38.5 million people; 1.4 million are living with HIV/AIDS. Out of that group, we've currently started 406,000 of them on antiretrovirals, with a current...[*Inaudible—Editor*].

My interest in this bill is because...[*Technical difficulty—Editor*].

By 2001, we had only 1,000 antiretrovirals. By 2005, about 10,000. These were drugs from big pharma. By 2005, PEPFAR came in with funds and some money came from the Canadian government. From the generics, we now have 406,000 people who are taking antiretrovirals.

If it were not for the generics, many Kenyans would have died.

● (0855)

**The Chair:** Mr. Kimani, just one moment. I'm sorry to interrupt you.

Monsieur Cardin.

[*Translation*]

**Mr. Serge Cardin (Sherbrooke, BQ):** The interpreter says it's almost impossible for him to translate what's being said because he can barely hear us.

[*English*]

**The Chair:** All right. Just give me a second.

I think the problem is with the connection that we have, Mr. Kimani. Sometimes the audio cuts in and out, and I think that's what's giving the translators the difficulty.

**Dr. Frederick Abbott (Edward Ball Eminent Scholar, Professor of International Law, Florida State University College of Law, As an Individual):** We just need to be careful because they're having some trouble with the Kenyan transmission.

**Dr. Joshua Kimani:** Is it very slow?

**The Chair:** Mr. Abbott, could you make sure that your mike is muted? That might be an issue as far as Mr. Kimani's transmission. Thank you very much.

Go ahead and begin again, Mr. Kimani. We'll see if that works better.

**Dr. Joshua Kimani:** Okay. Thank you.

As I said, I'm Kenyan...[*Technical difficulty—Editor*]...in Kenya and in Canada. I'm currently the clinical director for the Kenya AIDS control project, which is co-managed by the University of Nairobi and the University of Manitoba, in Winnipeg, Manitoba.

My interest with the bill is because I'm taking care of Kenyans who have HIV and AIDS. Kenya has a population of about 38.5 million, with 1.4 million living with HIV and AIDS. Currently, 406,000 are on the antiretrovirals, but this wouldn't be possible were it not for the generics.

If I go back in time, only 1,000 Kenyans were on antiretrovirals by 2001 when the big pharma were selling the antiretroviral drugs. By 2005, only 10,000 were on antiretrovirals. But something changed in 2005, when we started accessing generics from all over the world—from Brazil, from India—through PEPFAR, the presidential emergency plan for AIDS relief in Africa. We currently have 406,000 Kenyans living with HIV/AIDS on antiretrovirals, and that's a big jump. If it were not for those generics, the majority of these Kenyans would be dead.

In 2010 we changed the...[*Technical difficulty—Editor*...antiretroviral program to 350. This pushed the number of Kenyans who might go on antiretrovirals to about 610,000. This will require funding from some source. Currently, about 65% are funded by PEPFAR, and the rest are funded from other sources—global funds, pension funds, and Kenyans. But it's all generics.

With the previous association between Kenya and Canada, I think the only thing we need to get from Canada is generics. I know that somebody has said that generics can come from anywhere, but maybe the good people from Canada could invest in this, because with the increase in individuals on antiretrovirals for long periods, we expect a bigger number to become resistant, and not all antiretroviral drugs are in generic forms.

● (0900)

**The Chair:** Mr. Kimani, I'm sorry. We appreciate your time and everything, but with the connection we have it's almost impossible for me to understand. This has nothing to do with your capability and command of the language. It's the connection over the Internet.

I will leave it to our technicians to try to re-establish the connection so we can hear your testimony. For now we'll move on to Mr. Frederick Abbott and hear his testimony while we try to work on the connection with you so we can hear you more clearly.

**Dr. Joshua Kimani:** Thank you.

**The Chair:** Mr. Abbott, please keep your opening remarks to five minutes.

**Dr. Frederick Abbott:** All right. Can you hear me?

**The Chair:** We can hear you clearly, Mr. Abbott.

**Dr. Frederick Abbott:** Good morning.

I appreciate the opportunity to appear before the committee regarding the bill to enact proposed changes to the CAMR.

I appeared before this committee on March 10, 2004, during what was then consideration of Bill C-9, which, as amended, was ultimately enacted as the CAMR. In the course of dialogue with committee members in 2004 I raised several concerns regarding the terms of the then draft legislation. I was of the view that a number of the restrictions and limitations under consideration would hamper effective use of the legislation as then proposed.

Though some improvements were made in the legislation prior to its adoption, it was clear that Canada had decided not to take full or effective advantage of the flexibilities in the TRIPS agreement, the Doha declaration, and the August 30 waiver. It was foreseeable that limitations would significantly restrict the ability of the CAMR to address very serious public health problems confronting developing countries, with limited or no capacity to give effect to compulsory licensing. It's therefore not surprising that this committee is revisiting CAMR with the objective of making it a more effective and useful mechanism.

Let me spend a few moments explaining why I might reasonably be considered to have expertise on the subject of legislation to implement the August 30 decision. I've written and published extensively on the subjects of the TRIPS agreement, trade and IPRs, and on the relationship between that subject matter and public health, including access to medicines. I regularly have served as an expert consultant to the World Health Organization, the World Bank, the WTO, UNCTAD, and other multilateral organizations regarding trade, IP, and public health matters.

I served as legal consultant to the group of developing countries that formulated the proposal for the 2001 Doha declaration, worked with those countries throughout the process in which it was negotiated and adopted, and subsequently advised a core group of developing countries that was primarily responsible for negotiating the August 30 waiver at the WTO from the inception to the completion of that process. I have written and published about those negotiating processes in the *American Journal of International Law* and *The Journal of International Economic Law.*

I prepared for the World Bank a set of model-implementing legislation and documents for developing countries to implement the August 30 decision. I would note that one of my draft notification forms was used by Rwanda in its notification to the WTO. I've been to Canada again in the review of the CAMR. I've participated as an expert consultant at UNDP to reconsider this bill.

Finally, I would note, as a matter of disclosure, that I'm presently advising the Government of India in dispute settlement consultations at the WTO, where India and Brazil have initiated consultations with the European Union concerning the seizure of generic drugs in transit through airports in the European Union, and that Canada is a third-party participant in that set of consultations.

The August 30 decision has been criticized by NGOs promoting access to medicines, by some academics, by some generic producers, and by some developing countries for establishing an overly cumbersome set of rules that make it difficult to give effect to the basic objective of permitting export of low-priced generic pharmaceutical products to developing countries. I've consistently observed that the decision was a process of a long and intensive negotiation involving stakeholders with decidedly different perspectives, and that the August 30 decision represented a compromise between those perspectives.

Neither the NGOs seeking to provide the easiest mechanism for facilitating access to medicines nor the originator pharmaceutical industry found or find the August 30 decision to reflect an ideal world of either access to medicines or industrial protection. But my own view is that it can be made workable with appropriate implementing legislation and with conscientious work by lawyers, pharmaceutical procurement specialists, and others, in giving effect to the provisions of the August 30 decision. Nonetheless, for whatever reason, the CAMR was designed to add obstacles to the provisions of the August 30 decision, which make it more difficult to implement in practice.

Why the approach of Bill C-393?

Bill C-393 seeks to streamline CAMR to take advantage of flexibilities inherent in the August 30 decision by providing a pharmaceutical producer with the opportunity to obtain a single licence from the commissioner of patents that will authorize it to make and use a patented pharmaceutical invention for purposes of export to developing countries that identify public health needs.

● (0905)

A principal reason for proposal of the single licence is to solve a significant problem affecting the way international pharmaceutical procurement works in practice.

Many or most pharmaceutical procurement authorities acquire medicines by publishing a request for bids or proposals for supply of medicines, soliciting a response from industry. Competitive bidding isn't always practised. Nonetheless, it's extremely difficult for a producer, for example a prospective Canadian supplier, to respond to a bid request conditionally, indicating that supply is predicated upon obtaining a compulsory licence and that obtaining that compulsory licence may be a lengthy process that involves modifying a government list to add the subject-matter medicine to a list of products, opening negotiations with a patent holder or patent holders for a voluntary licence, and awaiting an ultimate determination by the commissioner of patents regarding whether a licence should be issued.

A public health procurement authority in a developing country would and should be understandably reluctant to award a contract based upon the fulfilment of an uncertain set of contingencies on the part of the producer-supplier.

Requiring a Canadian producer to request a compulsory licence on a case-by-case, country-to-country basis presents obvious difficulties. It presumes that a producer can and should develop a pharmaceutical production line to fulfill a single contract to be negotiated and put into effect over a protected period of time. But the licence is set to terminate after two years.

Simply put, you have heard and undoubtedly will hear from Canadian generic producers that this is a non-economic proposition. It's almost certain to drain business and personnel resources—

**The Chair:** I'm sorry to interrupt you—

**Dr. Frederick Abbott:** But you would like me to wrap up.

**The Chair:** Actually, I have extended as much leniency as I could. Can you wrap up in 15 seconds?

**Dr. Frederick Abbott:** Yes, let me just make a couple of points. One, there's nothing at all in the TRIPS agreement or the WTO August 30 decision that restricts a licence that would supply multiple destinations on the basis of a single licence. You would also look at the U.S. legislation that allows for government use of patented inventions of a mechanism with which Canada is intimately familiar, which allows the U.S. federal government to use any third-party patent at any time without notification to anyone and without any prior procedure. It is recognized as being compatible with the TRIPS agreement. So there is absolutely nothing in the TRIPS agreement or the August 30 decision or the chairperson's statement that prevents that kind of mechanism

I've otherwise submitted testimony with more details to the committee.

Thank you.

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

For the members of the committee and those observing, we're attempting to try to get Mr. Kimani on a separate telephone line and that way have a more clear connection with him. I don't like to do this, but I think for the use of time we're going to go to questions now. Once I'm advised by the technicians that we have him on the phone, we'll allow Mr. Kimani to continue his opening remarks. Again, because of the brevity of time we're going to go with five-minute rounds.

Mr. Garneau.

**Mr. Marc Garneau (Westmount—Ville-Marie, Lib.):** Thank you, Mr. Chair.

First of all, thank you to the witnesses for your presence here this morning. This is a passionately debated issue, and I want to say for the record that I subscribe 100%. I would be out at the front of the parade with respect to any mechanism that will assure that we can get HIV/AIDS, malaria and tuberculosis, and other medicines to those who need them in Africa. I want to make that very, very clear from the beginning.

Ms. Kiddell-Monroe, thank you for your testimony. I'd like to hear from you succinctly in your opinion why Bill C-393will, if not open the flood gates to this medicine that is so needed in countries...why it will solve the problem.

● (0910)

**Mrs. Rachel Kiddell-Monroe:** Bill C-393 actually specifically addresses some of the barriers that we saw in trying to use the legislation.

First of all, in terms of the countries and the notification, the system under the current regime makes a country declare its intention to the WTO to ensure compulsory licence. This is a huge barrier for developing countries when they face repercussions that they have from the U.S. government, from the European Union, and from pharmaceutical companies themselves. Bill C-393 will remove that barrier; that's the first thing.

The second thing is it's a one-licence solution. It simplifies it massively from the situation that we have now. It removes the need for the long period of voluntary licence negotiations. When there is a need there can be simply one licence issued by the Canadian government.

The other issue is that the proposed bill will remove the two-year limit on the compulsory licence and remove the quantity requirements. This is extremely critical, because what happened was that Rwanda made an order for a specific number of people, for a specific number of drugs. After they'd put in that order they realized that they actually needed more. In order for them to increase their order they had to go all the way back through the process from the beginning.

This new piece of legislation would remove that need. It will no longer require countries to be specifically identified; it will enable a licence to be given for an order for drugs for those countries that are listed. So that's how it still makes sure that it only goes to those countries that are listed, that are needed for this.

That will definitely go to the whole issue of creating a market. For a company like Apotex, while they said they would not use the CAMR as it stands again, they would, however, use the reformed CAMR as proposed under Bill C-393 and they deliberately said that they would produce a pediatric version of the Apo-TriAvir for export.

**Mr. Marc Garneau:** Thank you. I only have five minutes, so I'll have to hurry.

Dr. Attaran, you started out by mentioning that one of the main obstacles here is pricing, the fact that it is not financially viable for Canadian generic companies to provide generic drugs. Yet we're hearing a slightly different point of view. Could you expand a little on that argument, please?

**Dr. Amir Attaran:** It's very simple. What Apotex did was a stunt for publicity. They announced a price for a triple formulation and were unable to sell it for about two years. They then halved the price —it went from 38¢ a tablet down to 19¢. I may be off by a penny. They halved the price, made a single sale through Rwanda, and then they said they're not going to do this again. That's why it worked the one time.

Now, all the things that Rachel has mentioned, all the desiderata she has for amending the law, I have to say this: they have been tried in other countries. There are over 30 countries that have CAMR-like legislation: all 27 countries of the European Union, plus Norway, plus Switzerland, plus South Korea—I know I'm missing a few—China and India. Over 30 countries have this sort of law and many of them have no expiry date on the compulsory licence. Many of them do have what you'd call a one-licence solution. Nearly all of them don't have a list of countries that are intended recipients or a list of diseases to which it's limited.

And guess what? How many times have those 30-plus laws been used in foreign countries? Total? Zero. Zero invocations for zero treatments for zero patients for zero public health benefit. So this experiment has been tried abroad and I'm sorry to say it doesn't work. I wish it did, but it just doesn't. I know a lot of people will be angry hearing this, but these are the data. Unless you can say the data are wrong, end of story. Honestly.

**Mr. Marc Garneau:** Thank you.

**The Chair:** Very briefly, Mr. Garneau.

**Mr. Marc Garneau:** From the information that I've been given, I've been told that it took 68 days to sort out between the company Apotex and the three providers—the brand names, the manufacturers—the licence arrangement. It then took about a year for the first shipment to occur. Then, as you point out, there was a second shipment; it took another year for that to occur. So the argument that's been brought forward was that the brand-name manufacturers were quick to respond, and yet it took a very long time for Apotex to get these drugs to Africa.

Mrs. Kiddell-Monroe, do you have a comment on that?

● (0915)

**Mrs. Rachel Kiddell-Monroe:** They were very quick to respond to the first request for a voluntary licence, which was made quite early in 2005, with a 14-page lawyer's letter back for all the reasons why the companies were not able to accept, to issue a voluntary licence at that moment. Those actual negotiations are behind-the-door negotiations. I was not privy to those negotiations, but they went on for an extremely long period.

After the 68-day period, which I don't actually think is reflecting the true period of the negotiations, what happened then was that Rwanda went through its own systems of having to make a public tender in order to get different quotes from different companies. Apotex's was one of the quotes in there, and many of the delays were on that level.

This is a country's sovereign right to do the tenders process in the right way, which goes to prove that Apotex's activity was absolutely not a stunt, and I take great offence to that comment. This was a genuine effort to get drugs out to people. The reason why it could not be better was because of the restrictions—

**The Chair:** Thank you. We're way over time. I'm sorry that I have to interrupt.

Mr. Dearden, a 30-second response on this subject.

**Mr. Richard Dearden:** Because it's important to understand what happened when Apotex responded to Rwanda's notification, I'll give you some dates, members.

July 2007, Rwanda notified the WTO, as it's required to do under the decision.

Apotex applied for a CAMR authorization on September 4, 2007. That authorization was granted two weeks later, September 17, 2007. They had authorization to export 15,600,000 tablets. That authorization was given September 17, 2007. But one year later, September 23, 2008, Apotex ships half of that amount of tablets only. Then they apply for a renewal, so they didn't have to go through it all over again, as Rachel said. They had to apply for a renewal and got it six days later—

**The Chair:** Mr. Dearden, I've given a lot of latitude and time in trying to get a fulsome answer on that. You'll have to add that to the next one. I have to be fair to all members and their capabilities to ask questions.

I also have to go back to Mr. Kimani. We need to ask you if you have a telephone number we can reach you at so we can get a separate connection to you in order to be able to get the audio clearly to us.

Mr. Kimani, can you hear me right now? Is your microphone muted, Mr. Kimani?

His screen is frozen now, so we'll move on to the next questioner and we'll try that again.

Now on to the Bloc.

[*Translation*]

Mr. Malo, you have five minutes.

**Mr. Luc Malo (Verchères—Les Patriotes, BQ):** Thank you, Mr. Chair.

I want to thank the witnesses for joining us.

At our previous meeting, last week, we had with us Dr. Kilby. He told us that, by the end of the year, 5.2 million patients will have been treated, but that it was already clear that the supply from India could not meet those needs. He said that many of his patients will need second-generation medicines because the toxicity level of first-generation medicines is too high. He also told us that in the coming years, he will be able to treat twice as many patients. It's obvious that there won't be enough generic drugs for all those people.

Dr. Attaran, you said in your presentation that our Parliament does not have the power to optimize the current system and make it possible to get medicines to the poorest countries. We are talking about the countries Dr. Kilby mentioned in his presentation.

I ask myself one simple question on the subject. Drugs are needed to meet the needs. If we are unable to provide drugs because of their cost, how can supplies be shipped to those countries? That's the key question people are asking. How can we do more to resolve this problem?

● (0920)

**Dr. Amir Attaran:** That is a very good question. We do have a serious problem in the fact that the virus mutates. It's evolution just as Charles Darwin laid it out. After a few years, first-line medicines are no longer effective. We now need second-line medicines. Fortunately, they are available in countries like India, for instance. India is actually the largest supplier of second-line drugs. The fact that Canada cannot provide those medications doesn't mean they're unavailable. They are available elsewhere.

I believe that you asked what we can do here, in Canada. I already mentioned that there are serious problems with CIDA, which is not a very effective donor, among other things. Even if we are unable to supply the required drugs, we can still provide money, technical assistance, and so on. I'll give you one example. Since counterfeit medications can cause death, a child with malaria who is given counterfeit tablets will die because the tablets don't actually contain any medication. We can provide technical support to help avoid similar outcomes in countries that don't have laboratories for drug testing.

**Mr. Luc Malo:** Last week, Dr. Kilby told us that Indian regulations on patented medicines prohibit the shipping of second-line generic medicines. Yet, today, you are saying—

**Dr. Amir Attaran:** That is totally false. India has legislation that is almost identical to Canada's Access to Medicines Regime. Pardon me, but I will have to explain this in English.

**Mr. Luc Malo:** Go ahead.

[*English*]

**Dr. Amir Attaran:** I cannot emphasize this point enough. There are over 30 countries with CAMR-like laws. In the wake of the WTO decision, Canada was the second country to pass a law. Norway was first, we were second, but then about 30 more did, including all 27 countries of the EU. If none of those other countries has succeeded in making this type of law work, that should tell us something. But bear in mind that because those other countries do have similar laws and their generics are less expensive than Canada's, it would be those laws, if ever they were useful, that would be used first.

Look, it's just an act of tremendous hubris to think that Canada is the solution to the world—we're not. We're not the solution to this particular problem. There are areas where we can be a solution, and by God we should be, but this is not one of them, I'm sorry to say.

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

Thank you, Mr. Malo.

We're now on to Mr. Lake, for five minutes.

**Mr. Mike Lake (Edmonton—Mill Woods—Beaumont, CPC):** Thank you, Mr. Chair.

Thank you to the witnesses for coming today.

Ms. Kiddell-Monroe, while you and I may disagree on some aspects of this, I definitely appreciate the passion that you have for the issue. It's clear that you have a tremendous passion. And around this table—and from what Mr. Garneau said as well—if the question is do we want to help the people of Africa who are suffering, absolutely, I think that you'd find agreement all around the table and in this room. The question we're trying to answer today is does Bill C-393 actually accomplish this, or are there other things that are working or that we should be focusing on to accomplish this?

I go back to Mr. Kilby's testimony before the committee here the other day, when he was talking about the numbers of people who are receiving antiretroviral drugs. He talked about the numbers in 2003 and he said that 400,000 were receiving those drugs; by 2005 we got up to 1.5 million; and by the end of 2010 we expect to get to 5.2 million people being treated. That seems like a significant number. In fact Mr. Kilby, to quote him from the meeting, said:

> Essentially a comprehensive model for care many believed could never be built emerged in a few short years. What has been accomplished is nothing short of a miracle, 5.2 million people on treatment by 2010.

Do you agree with what Mr. Kilby had to say regarding the progress?

● (0925)

**Mrs. Rachel Kiddell-Monroe:** Yes, I absolutely do, and I think that is because of the entrance of generic competition into the market and bringing down the prices. That's exactly why that has been accomplished. We also have to remember there are still nine million people who have HIV/AIDS who do not have access to treatment. Those people are desperately in need. There is still a huge need, and the second-line, third-line drug issue is a big issue.

India is not going to be the solution to that. One of the big reasons is that many of those drugs are under patent in India. Due to its compliance with the WTO from the first of January 2005, it can no longer just produce many of those drugs under generic versions, so its prices will be higher.

Canada has a role to play in order to bring another player into the market, have their generic companies.... When Apotex came into the market, it forced Indian companies to go and make sure that their drugs were of adequate quality and get them pre-qualified with the WHO program. This was a hugely important aspect of what Apotex managed to do.

If the limitations are taken off, as would be the case under Bill C-393, we would be able to provide another player in the market, which would encourage competition.

**Mr. Mike Lake:** So in terms of what Canada can do, you talked about that, and one thing that we know from previous testimony, Mr. Attaran's testimony today, is that other countries are producing those drugs and making them available much more cheaply than Canada can.

What we do know is working is the funding of the global fund now. The government just announced a third replenishment of $540 million from 2011 to 2013. That's a 20% increase from the last replenishment here in Canada, and I think $1.5 billion since its inception in 2002—very, very significant.

Speaking to what Canada can do to have a significant impact, not so concerned with where the drugs are coming from or whether they're coming through CAMR or through some other mechanism, I would think that we can agree that the most important aspect of this is that drugs are actually being received by the people who need them, to the tune of over ten times as many as were being treated in 2003.

**Mrs. Rachel Kiddell-Monroe:** The question is the sustainability of that increase, and if we need new lines of drugs that are being protected under patents—and they're not being produced all over the place, as seems to be implied at the moment, for distribution—then the problem is not going to be improved. Of course, while we have the first line, they can use them.

The issue about other countries having this legislation in place is that many of them have not tried to use their August 30 legislation. One of the reasons was that they were looking to Canada to see how Canada would behave, how Canada would be able to make it work, and many countries are still waiting to see that.

There will be new discussions at the WTO about the August 30 decision and why it's not working, and how to make it a functional thing. I believe we need to have more solutions on how to get the correct medicines to people. The second line of the AIDS crisis is showing that.

**Mr. Mike Lake:** So you and I would agree that we need to take a look at what the next step is, but we need to identify systems and programs that are actually going to work to go from the $5.2 million to address the totality of the situation in Africa.

Mr. Attaran, did you want to comment?

**Dr. Amir Attaran:** Yes. I really must say I found Rachel's answer not properly analytic on this issue.

Let me be very frank. She said that other countries are waiting to see what Canada does before invoking their CAMR-like laws. That hypothesizes that China, India, and the European Union aren't clever enough to figure out how to do it themselves and need Canada to show the way. This is just unreal. Those are very sophisticated countries, as is Switzerland, as is Norway, and if they want to make use of their own laws passed by their own parliaments, they really don't need to watch and wait and see how Canada does it.

I'll leave it at that, but on the suggestion that there wouldn't be in the future medicines such as the second-line medicines available from those other countries that would only be available in Canada, again, that doesn't make a lot of sense. We're a relatively minor industrial country. We're small. We're no India. We're not China. That's obvious. We're not even the European Union. Thank goodness we can manufacture medicines and do it well, but so can those others, and this is inherent in the nature of globalization. There is more than one source for these things, and I would be shocked, I am shocked, to hear the advocacy that says “Although Canadian generics cost more, we want people buying those”, because that means fewer patients treated.

● (0930)

**The Chair:** Thank you, Mr. Attaran. I'm sorry, but time always bedevils us here at the committee.

Now we go on to Mr. Masse, for five minutes.

**Mr. Brian Masse (Windsor West, NDP):** Thank you, Mr.Chair.

Mr. Attaran, you've actually convinced me, as someone who has sat through this entirely over the last number of years, even when this was Bill C-56, to continue my efforts even more than ever before. Even looking at the face of your argument, you're actually advocating for generic rip-off drugs to get to people, as opposed to Canadian drugs. That's what would happen and would continue to happen under your scenario.

You used the word “unethical” in terms of the medical aspects of this. I find it unethical.... If you don't believe in Bill C-393, then come here with a solution that's actually going to help. I stood in the halls of Parliament when we all stood together to say that we wanted to make a difference, wanted this law to actually work.

I want to use my time with Mr. Abbott, who has actually been there. Mr. Abbott has spent his time at the WTO, has spent his time on the TRIPS, has advocated for a number of different groups and organizations.

Mr. Abbott, we've heard from the department and the lawyers here that we're going to violate pretty well every international treaty under the sun—now including NAFTA—by working on this bill, but at the same time that this bill won't even work. It's an interesting scenario, but I would like from you your testimony about why Canada won't be violating any international agreement by changing this bill, or how we can do it.

**Dr. Frederick Abbott:** Thank you very much, Mr. Masse.

It is pretty clear, as a matter of the TRIPS agreement and the August 30 decision, that it is perfectly permissible for Canada to adopt a single-licence solution in which a substantial quantity of drugs is provided over a period of time. There is no requirement in the August 30 decision that the sequencing involved in the Canadian legislation be followed. Provided that notifications are provided at the time the drugs are shipped, Canada will have met all of its international obligations.

Let me add another point. There is no country in the world that is going to initiate a dispute settlement action at the WTO against Canada for providing low-cost drugs to poor people in developing countries. I repeat, no country in the world is going to bring a dispute settlement action against Canada for providing low-cost HIV antiretroviral medicines to people in developing countries at low prices.

Even assuming there were a morally and ethically challenged country that would do that, the worst-case scenario for Canada would be that after a period of three to five years it would have to fix what might be considered wrong with its legislation, and Bill C-393 is not inaccurate.

I want to make one other point. This argument by Mr. Attaran I find absolutely astonishing—and that Canadian parliamentarians are actually caring to echo it. His argument basically is that Canadian pharmaceutical producers are incompetent and cannot compete on global markets. And because they are incompetent and cannot compete on global markets, we should not let them compete on global markets. It's as if to say that because Canadians are not very good at playing basketball we should prevent Canadians from playing basketball and from joining any league that plays basketball.

Apotex supplies a large quantity of drugs to the highly competitive U.S. market. Teva Novopharm is one of the most competitive and largest suppliers of generic drugs in the world. The idea that Canadian industry is unable to compete with Indian industry—and I represent the Indian industry—I find absolutely an astonishing argument for preventing them from attempting to compete.

What are we talking about? We're talking about changing a few words on a piece of paper in Canada: we let you compete. The argument from Mr. Attaran is that we shouldn't change the piece of paper; because they are providing higher-priced medicines, we should foreclose them from competing. I really just find this argument so nonsensical it's hard for me to believe that a group of parliamentarians is sitting in a room accepting it.

I apologize for going on like that, but it's just such a nonsensical argument.

● (0935)

**Mr. Brian Masse:** Thank you, Mr. Abbott. I want to follow up, though, on one of your statements.

If there were that country out there—and I've contested that.... You would have to have a case in Canada in which we were providing treatment for people who are suffering and dying, and another country would then intervene to try to stop that from taking place, to deny those people that treatment. If there were that country out there and that case went forward and we lost—these are big ifs—we still have time to fix the bill to comply.

Is that not the case?

**Dr. Frederick Abbott:** That is the case. The only WTO theoretical dispute settlement penalty is to request Canada to bring its legislation into compliance with the determination of the dispute settlement panel. There is no penalty; there is no monetary fine. Frankly speaking, I think Canada would gain greatly in the opinion of the world community were someone to bring a lawsuit against them at the WTO alleging that Canada was trying to do too much for poor people in developing countries.

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

Thank you, Mr. Masse.

Before we go on to the next round, I'm going to make one more attempt to see whether we have a good connection with Mr. Kimani. In advance I'll ask Mr. Abbott to mute his microphone, and we'll see whether we can get Mr. Kimani.

Can you hear me, Mr. Kimani?

**Dr. Joshua Kimani:** Yes. Can you hear me?

**The Chair:** Yes. Could you try your opening remarks again? I will ask you to be as brief as possible, and we'll see whether we can have a smooth transmission this time.

**Dr. Joshua Kimani:** I am Joshua Kimani. I'm a medical... [*Inaudible—Editor*]...individuals in Kenya. I live and work in Kenya.

Is that clear?

**The Chair:** No, it's not Mr. Kimani; I apologize. I think the only thing we can ask you to do is to submit your comments to our clerk via e-mail and we'll have them translated for the committee. I apologize that we just weren't able to get the technology to work properly.

Okay, now we'll go on to a second round of five minutes. We are going to need to be a little bit more disciplined at the five minutes this time. I apologize for any intervention.

We'll turn to Mr. Rota for five minutes.

**Mr. Anthony Rota (Nipissing—Timiskaming, Lib.):** Thank you, Mr. Chair, and thank you to the witnesses for coming out.

There has been a lot of concentration on India as the country that's producing the drugs, the antiretrovirals, but as of 2005 patent laws are changing, and there's a clear shortage. There's going to be a shortage of drugs in third world countries because India is not producing or not able to export. What countries are taking up that slack? Do we see countries coming up?

We'll start with Mr. Attaran very briefly and then go over to Mr. Abbott, if you don't mind.

**Dr. Amir Attaran:** Thank you, Mr. Rota.

India has increased its manufacturing capacity. It is a very large country. It can lay on new assembly lines and it has done so. As India comes under the patent regime, I agree that this is a challenge. But India is best placed to solve it, because India, remember, also has a CAMR type of law. If conceptually a compulsory licensing law can help, it stands to reason that it will help in the country that is already best practised at making these medicines for export and does so at a lower price.

There's also—

**Mr. Anthony Rota:** Let me just add to that. India is also a very growing country; it's developing very quickly, and their own needs are growing tremendously. Their demand internally is probably going to rise. How can we depend on that country to export, when their own production inside is so—

**Dr. Amir Attaran:** We're not solely dependent on them. And as I pointed out, there are over 30 countries that have the CAMR system. I don't think India will run into that limit, but let me assume you're right. If they do run into a limit, there are 27 countries in the European Union that can pick up the slack. There's Switzerland, which has an enormous pharmaceutical industry—little Switzerland has a much bigger pharmaceutical industry than we have in Canada; there is Norway; there is China. So we're not really short on countries having CAMR-like laws that could invoke them.

May I add one other thing? I want to respond to some of what was said. You know that you're doing well in an argument when people put words in your mouth. I'm very distressed to see Professor Abbott very untruthfully say that I called Canadian generics "incompetent". I did not.

● (0940)

**Mr. Brian Masse:** On a point of order, Mr. Chair, we have a witness who is saying that another witness is lying. I haven't seen that type of behaviour at a committee in all my years here. To say that it's untruthful—

**Dr. Amir Attaran:** I did not say the word “incompetent”, and I don't believe it.

**The Chair:** Yes, Mr. Lake.

**Mr. Mike Lake:** I honestly think Mr. Abbott made some strong comments regarding Mr. Attaran's testimony. Mr. Attaran has the right to defend himself.

**The Chair:** For the committee and for the witnesses, I understand the magnitude. It's a very serious issue and a very emotional issue. But please keep your remarks with a level of respect and dignity; that's required here in the committee as well.

Mr. Attaran, please continue.

**Dr. Amir Attaran:** Thank you, Mr. Chair.

I did not call Canadian generics incompetent. That is not the case, and the record will show that. What I did say is that they are more high-priced than other generic producers. This is simply a reality. Don't shoot the messenger. That's what the federal government admitted here—

**Mr. Anthony Rota:** Thank you, Mr. Attaran. I only have five minutes here, and I'd like Mr. Abbott's take on this as well.

Mr. Abbott.

**The Chair:** Mr. Abbott, start again and unmute your microphone. I think you muted it for Mr. Kimani last time.

**Dr. Frederick Abbott:** Thank you very much.

As you noted, India has considerable capacity. India is facing new challenges as the 2005 patent law amendments take effect, and its newer drugs will fall under patent protection and then be less amenable to large-scale domestic production. India just finished convening a working group and a review process with regard to its compulsory licensing legislation. I returned from New Delhi on Sunday. When I was in India last week I was advised that there are generic producers in India preparing to make use of India's article 30 implementing legislation in the not distant future, to determine how well the Indian system is working.

I would certainly hope that Canadian generic producers, like Apotex, are willing to compete head-on with Indians in the supply of drugs to poor people in developing countries. I have no reason to believe that your producers are not capable of also stepping in. I would add, as these drugs become the more sophisticated second-line and third-line drugs, fusion inhibitors, etc., this is where Canada may really excel with very sophisticated synthesization techniques for higher-end and more complex antiretroviral drugs. I think there's a major role for Canadian industry to play in this area, and I cannot imagine why you would say that because Canadians are not very good at competing in the international market on price, we will bar them from competing. It simply makes absolutely no sense at all.

Thank you.

**Mr. Anthony Rota:** I have 30 seconds but my question takes longer than 30 seconds.

**The Chair:** Thank you very much, Mr. Rota.

Now to Mr. Braid for five minutes.

**Mr. Peter Braid (Kitchener—Waterloo, CPC):** Thank you very much, Mr. Chair.

Perhaps I can start with some questions for Mr. Dearden.

Thanks to all of you very much for appearing this morning and for your important testimony.

Mr. Dearden, we appear to have two different lawyers with two different opinions this morning. I know that's not a shocking revelation. Could you speak to that very quickly?

Then I have a second question for you. You spoke about compulsory licence obligations. I want to ask if you could clarify exactly what those are, and we'll proceed from there.

**Mr. Richard Dearden:** I'll go in reverse.

The compulsory licence obligations are set out in article 31 of the TRIPS agreement. That goes from paragraph (a) to paragraph (l) in terms of conditions that must be met for a member such as Canada to authorize compulsory licences. One of those that I mentioned in my opening remarks was that you were allowed to issue a compulsory licence under TRIPS only if it was predominantly for domestic use, so that made it useless in terms of the solution we're talking about today, which is to export.

So then the WTO—and this is crucial, I think—had to come up with a solution to getting around that compulsory licence obligation that it could be issued predominantly for domestic supply only. Mr. Abbott knows full well, because he was there during the negotiations, that one of the options on the table was to use article 30, the limited exceptions. That was rejected by the WTO membership, presumably, as was stated by the 2007 statutory review, because it wasn't seen as a way to do this. So they had to have a waiver, and the waiver is what we see in the council decision. There are mandatory obligations, among other places in paragraph 2, and they all start with notification by the importing country, the country that wants it. Then the compulsory licence has to have conditions in it that deal with necessary amounts, quantities, duration. All of that's in there. It has to be there. Then Canada, sir, is obligated to notify of products, quantities, and duration of licence as part of its international obligations.

What I think you're really hearing here is that the root of the problem is not CAMR; the root of the problem is what was negotiated with all those stakeholders that Mr. Abbott mentioned to us, because they were all in play. The root of the problem was that decision. But this is not the forum for solving that problem by implementing legislation that Professor Abbott is so boldly saying no one will dare challenge. That's his opinion. The solution is in Geneva, and indeed they're working on it now. They're reviewing whether or not the decision is doing what it's supposed to do, and there's an all-day meeting tomorrow over in Geneva to review how the decision is working.

Could I use your time, Mr. Braid, to get on the record the one and only time it has worked in the world? That was Apotex, in the Rwanda situation.

I would like to put this on the record, Mr. Chair, if I could.

● (0945)

**Mr. Peter Braid:** You could do that, and then I have one quick question I still want to ask you.

**Mr. Richard Dearden:** I will.

I told the committee that Apotex had the authorization on September 17, 2007, to export 15.6 million tablets to Rwanda, because that's what the authorization let them do. It took them a total of two years to ship that. CAMR worked, committee members. They got their licence within two weeks. They got their renewal in six days. It worked.

**Mr. Peter Braid:** Thank you, Mr. Dearden.

If WTO and/or NAFTA agreements are violated by Canada, what does that mean for Canadians? What does it mean for Canada as a country? What does it mean for Canadian citizens and/or consumers? What are the consequences?

**Mr. Richard Dearden:** I think Professor Abbott was fair in saying that there is no fine. That's true. But does Canada respect its international treaty obligations? It just signed up to make the waiver a permanent amendment to TRIPS. In my opinion, it matters that Canada would comply with its international trade obligations. There is no fine, as Professor Abbott rightly said, but then you have a strategy whereby you say let's violate the law and we'll rag the puck for five years in litigation and then when we're told to fix it we'll fix it then, but in the meantime we'll have five years of illegal exports, or exports that don't comply with the decision.

**Mr. Peter Braid:** Thank you.

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

**Mr. Peter Braid:** Mr. Chair, could I just very quickly mention something? There was a reference earlier to Canadians not being able to play basketball. Steve Nash, a Canadian, was NBA MVP of the year twice in a row.

**The Chair:** Thank you, Mr. Braid. I'm glad everybody was brought up to speed on that.

Now we go to Monsieur Bouchard, *pour cinq minutes*.

[*Translation*]

**Mr. Robert Bouchard (Chicoutimi—Le Fjord, BQ):** Thank you, Mr. Chair.

Good morning, ladies and gentlemen. Thank you for your testimonies.

I have two short questions for Mr. Attaran. My colleague Mr. Cardin will ask a third question.

You said that here, in Canada, generic medicines are more expensive than elsewhere. There's less competition in the production of generic medicines here. Is that the main reason behind higher prices in Canada?

● (0950)

**Dr. Amir Attaran:** Probably not. Where economic matters are concerned, there are always several factors, several reasons that we can point to and, in this case, one of those reasons is certainly the lack of competition. In addition, perhaps Canadian manufacturers are used to being more profitable than foreign companies. I don't know.

**Mr. Robert Bouchard:** Correct me if I'm wrong, but you said earlier that we should forget about Bill C-393, CAMR, because it doesn't work. We should, instead, direct our energies toward other kinds of reforms.

What do you suggest Canada do to help the cause?

**Dr. Amir Attaran:** May I answer in English?

**Mr. Robert Bouchard:** Yes.

[*English*]

**Dr. Amir Attaran:** Merci.

We have to be pragmatic about what CAMR can and cannot do. A bit of a strange argument occurred to me while sitting here, but I'll make it, really out of intellectual curiosity more than anything else.

You could make the argument that the CAMR is the most successful law of its kind in the world and that it shouldn't be messed with, because it has been used once, whereas the other 30 countries together have used theirs zero times. Now, I know it's a very strange argument to make that it's "successful", but you could look at that reasoning as saying "Do nothing, because if it ain't broke, don't fix it".

I think fixing it, as it were, or changing the law, is not likely to make this law more or less effective. It's going to be barely effective. You therefore are better off—and this is why I so appreciate your question, sir—looking at the other things you can do for global health. It is completely sick that there are billions of people at risk of very minor diseases, millions of people a year dying of AIDS and malaria. This is just completely unacceptable. But if we're going to be intelligent about it and not be bleeding hearts, we're going to ask ourselves, where is our specialty? What is it that we excel at that we can best do to help—while admitting there are another 30 countries with laws that are, in some respect, superior to CAMR and who are helping in this area? I think that's the wise way to go about it.

Where we can help is certainly in funding, and certainly in training. We're one of the few places where you can go to university in English or French. We can train scientists, technicians, and physicians from developing countries to work in health systems there. We can provide assistance to stop problems like the counterfeit generics. And, Mr. Masse, you very much misrepresented me in saying that I was advocating for these medicines. I'm not. I condemn them.

**Mr. Brian Masse:** No, I didn't. I'll stand by my record and my word.

**Dr. Amir Attaran:** I'm sorry that you do.

**Mr. Brian Masse:** I'm not.

**Dr. Amir Attaran:** But the reality is that there are other things that can be done and must be done. We excel in the technical field. So let us train. Let us provide laboratory assistance. Let us provide greater foreign aid funding. The government has recently increased contribution to the global fund. Bravo. Let's increase it some more. Those are things that we can and should do.

But please, all of you, recognize that this law has not worked. CAMR has not worked. Do not throw more good time after bad, and let's shift to the things that will make a greater difference. Let's not be ideological; let's simply be pragmatic.

**The Chair:** I know that Madam Kiddell-Monroe has a quick comment.

Could you do that quickly, because Monsieur Cardin has one more question.

[*Translation*]

**Mrs. Rachel Kiddell-Monroe:** I have a very quick comment to make, Mr. Bouchard. I don't think that there's only one possible solution. There are many initiatives Canada could undertake. Bill C-393 is one of them; it can help. There are certainly other initiatives that could be undertaken. The Global Fund to Fight AIDS, Tuberculosis and Malaria is very important. The funding Mr. Lake talked about earlier is a very important Canadian contribution.

Canada can also help without Canadians incurring costs. It can do that by simply letting our pharmaceutical companies, our generic medicine manufacturers, do their work properly. Those companies have developed very specific products that could really have a major impact on the global health scene.

● (0955)

[*English*]

**The Chair:** Thank you, Madame Kiddell-Monroe.

Very briefly, Monsieur Cardin.

[*Translation*]

**Mr. Serge Cardin:** I have some comments to make.

Thank you for being here.

Following up on Ms. Kiddell-Monroe's comment, I must admit that problems do exist. First of all, people are dying. Second of all, money is an issue. In addition, as you said at the beginning, we are currently part of an almost undemocratic process because sponsorship is not ensured.

The first step would be to at least refer the bill to the House, so that the matter can be decided. However, serious doubts could arise, as some people might have different goals in mind.

The bottom line is that people are dying. Money is also a problem. You mentioned the Global Fund to Fight AIDS, Tuberculosis and Malaria, which is set at $13 billion a year. You say that Canada is contributing. We were told last week that Canada contributes $150 million or $160 million to the fund, which is about 1% of the total amount.

Companies also worry about money, but they often forget that dying people will never buy highly priced drugs. That much is obvious. How much could pharmaceutical companies contribute to the cause? Either way, they will never sell those people anything. Consequently, they might as well sell their products at no profit, or even at a small loss.

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

[*English*]

Now we're on to Mr. Wallace. Mr. Wallace, we have two more groups of people, so would you keep it as tight as you can, please?

**Mr. Mike Wallace (Burlington, CPC):** I actually only have one question, Mr. Chair, and we'll deal with that. I want to thank, first of all, our panel and our guests by video link who are joining us today.

I want to stick to the actual bill that's in front of us, and I'm going to ask Mr. Dearden a question and the same question to Mr. Abbott. Under the bill there is a change. At present, any drug leaving the country is approved by Health Canada. In the bill there is an option to have it approved by Health Canada or not, based on what the receiving country wants. I don't know the answer to this question: does that leave Canada with any legal liability because they're not exercising the opportunity to evaluate the drug before it leaves the country?

I'm assuming we have a liability now, since we've approved it. If we don't approve it, do we carry a new liability as a country? There are more than two legal minds here, but there are two people I've indicated to answer that question.

**Mr. Richard Dearden:** There's a third one to my left.

**Mr. Mike Wallace:** And a fourth.

**Mr. Richard Dearden:** The requirement in CAMR now for Health Canada approval actually isn't mandated by the general council decision, but I don't think anybody, the generics or the innovative drug industry, object to the requirement being in there that safe drugs actually do get exported under the compulsory licence system.

My problem, Mr. Wallace, with any drug is that the "pharmaceutical product" definition in the general council decision was looking at epidemics and serious problems, not lifestyle drugs. Bill C-393 is offside, in my opinion, because it applies to all drugs, not the ones that we see in schedule 1, which is a limited list. That puts it offside there.

My colleague also wanted to add something, so I'll give him my time.

**Mr. Mike Wallace:** We'll go to Dr. Abbott first—is that all right?

**Dr. Frederick Abbott:** Well, Mr. Dearden is correct that there is nothing in the WTO rules or dealing with the WTO that regulates the quality, safety, and efficacy of drugs. From that standpoint, there's no liability.

Secondly, as a general proposition, virtually all countries maintain domestic regulatory authorities that are responsible for determining the quality and approving the drugs that are put on their domestic markets. But in this case there is an even more practical issue and solution to what you're mentioning.

Virtually all of the antiretroviral drugs being supplied in large quantities into Africa are being supplied under the terms of large-scale procurement funding that is coming from multilateral organizations and donor funds like the global fund. All of those funds require that the drugs that are being purchased meet strict compliance guidelines. Those strict compliance guidelines may often be and are typically the WHO pre-qualification program.

As a practical matter, the notion that Canada would be exporting unqualified or unsafe drugs under this system is very unlikely, and I would just end with that.

● (1000)

**Mr. Mike Wallace:** If the other two have any comments, I'd be happy to hear them.

**Dr. Amir Attaran:** Thank you for giving me the time.

I'm going to draw attention to something that Mr. Abbott said. He said that medicines sent abroad have to comply with "strict compliance guidelines". Those were his words. He's right.

Strict compliance guidelines are not the same as law. Law is different from guidelines. Having it in the law, Mr. Wallace—because you did ask about the bill—that Health Canada must exercise the same regulatory oversight for medicines that are exported under CAMR as for medicines taken by Canadians...that's actually the only correct way to do it, not guidelines that aren't legally binding.

There is a problem that has been experienced in Europe. I have to be coy in these comments because a colleague of mine who spoke about this publicly was sued.

There is a European country in which there is a European company that supplies malaria medicines to Africa, some of which are substandard. Why? It's because the unnamed country's law allows medicines to be exported from Europe to Africa that do not meet the regulatory standards of the European country itself. This has certainly resulted in patients getting the wrong sort of treatment.

The tactics are so brutal in this industry that another professor was litigated against for even bringing this up.

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

Madam Kiddell-Monroe.

**Mrs. Rachel Kiddell-Monroe:** Thank you very much.

These two points, the list of medicines and the Health Canada approval, are both above and beyond what's required by the WTO. These were things the Canadian government decided to add in those negotiations; they are not necessarily according to WTO standards. If the argument goes that we should just refer to what the WTO says, we don't need them to be in there.

**The Chair:** Thank you very much, Mr. Wallace.

Thank you very much to our witnesses, both here as well as abroad. We appreciate your testimony.

If members want to speak to the witnesses as they leave, I would ask them to please take it outside. We need to shift from these witnesses to another group for the next hour and a half, and we would like to do that as efficiently as possible.

We'll suspend for five minutes.

● _____ (Pause) _____ ●

● (1005)

**The Chair:** Ladies and gentlemen, we're now back in session. I'm going to introduce the witnesses at the table.

We have, from Doctors Without Borders, Emilou MacLean, who is director of the United States of America Campaign for Access to Essential Medicines. We have Grant Perry from GlaxoSmithKline Canada, vice-president of public affairs and reimbursement. We have, from the National Advocacy Committee of the Grandmothers to Grandmothers Campaign, Elizabeth Rennie and Linda Watson. From Apotex Inc., we have Bruce Clark, vice-president of regulatory and medical affairs. From Canada's Research-Based Pharmaceutical Companies, we have Russell Williams, president, and we have Laurence Dotto, director, government and external affairs.

Then we have, by teleconference, Angus Livingstone, managing director, University-Industry Liaison Office, University of British Columbia.

Who is going to make the opening remarks for the Grandmothers to Grandmothers Campaign?

Okay, if you would, please begin now, Ms. Rennie, for five minutes.

**Ms. Linda Watson (Member, National Advocacy Committee of the Grandmothers to Grandmothers Campaign):** May I make one comment to explain this box?

**The Chair:** Certainly, but it will be part of your time. Go ahead.

**Ms. Linda Watson:** I'll just say that we have brought in this morning 3,000 additional pieces of correspondence, and more has been added just now, to the already 9,000 pieces of correspondence that have come from Canadians across this country to this committee in support of Bill C-393.

**Ms. Elizabeth Rennie (Member, National Advocacy Committee of the Grandmothers to Grandmothers Campaign):** We express our appreciation to Mr. Sweet, the chair of this committee, and to the committee members for hearing our brief on this bill.

We present as concerned grandmothers and granddaughters from across Canada. With me are members from British Columbia, Quebec, and Nova Scotia.

The Grandmothers to Grandmothers Campaign is made up of 240 groups—that's 10,000 people—across Canada. In addition to that are the thousands of others we call “grandothers”. In fact, a Pollara poll in 2009 indicated that 80% of Canadians want this bill passed.

We're concerned about the plight of African grandmothers. Why Africa? Because that is the region where, as you know, they are most heavily inflicted with the HIV pandemic.

This, ladies and gentlemen, is a pandemic that has hit the children: 13 million children are without either one parent or both.

This, ladies and gentlemen, is more than the total of all the children in Canada and Norway.

This is about women and children. The toll is particularly hard on those in developing countries. AIDS is the number one killer of babies. In fact, in the region of sub-Saharan Africa, most children who are HIV-positive die before the age of two.

Can you imagine, even for one minute, what it would be like to bury your children and then to take on the responsibility of raising two or four or ten orphans, very vulnerable children and adolescents? I met some of those people when I was in Africa.

What would it be like for Canada to be defined as a country that has lost a generation of workers, of adults? These parents, teachers, nurses, workers would be alive if they'd had the life-saving treatment that they couldn't afford.

Having highlighted the effect of HIV/AIDS on women, it's imperative to recognize that it is the women in sub-Saharan Africa who are literally holding that continent together because of their positive actions and their determination to stem the tide of this pandemic spreading. This can only happen if we increase the supply of affordable medication to them.

We have read the reports and the studies. We have visited MPs. And we have listened to the concerns. Your colleagues will tell you, as Linda has already indicated, that we have had responses from thousands of Canadians.

This is evidence that Canadians care. Canadians care. And it is our belief that there should be universal access to health care.

Canadian grandmothers are not naive. We know that passing this amendment without changes is but one solution. It's not a panacea. We know that. But we certainly question the wisdom of rejecting a viable solution and proposing the creation of another mechanism.

The argument has been raised that Canada must first address the issue of poverty. It's not a case of either/or. Each consideration regarding poverty infrastructure is hugely important. They all form the multi-faceted response that is needed to save lives and communities. But the fact is that there are places right now, even with drugs from China and India, where people who have infrastructures and who have water are being forced to remain on waiting lists until someone in the community dies before they are able to receive the medication. Treatment matters, and it matters now.

● (1010)

This debate should not be about patents or intellectual properties; it should be about people. It should not be about patent protection over human lives. This is a humanitarian bill. This bill is about people like you and me.

In May some of us went to Africa, and what was theory before is now reality. The statistics of millions took on a face. She has a human face and she lives a courageous life. Being in Africa for just over two weeks did not make us experts—we don't pretend that it did—but we didn't go as tourists. We went to listen and to learn.

We heard heart-wrenching stories. We walked, talked, ate, and danced with women from Kenya, Malawi, and Swaziland—from 13 African countries. Their requests had a common theme: "We know what to do. We know what we need. Support us. Be our voice in Canada."

● (1015)

**The Chair:** Thank you, Madam Rennie. I'm sorry, but we're well over time now.

**Ms. Elizabeth Rennie:** I know there are a lot of statistics. May I just tell one story please, Mr. Chair?

**The Chair:** Do you mind if we give her one more minute, just to finish?

**Mr. Mike Lake:** Yes, if there's agreement in the committee.

**The Chair:** Go ahead, Madam Rennie.

**Ms. Elizabeth Rennie:** Thank you very much.

I listened to a woman in South Africa tell her story. This is a woman who has a face. She had taken her four-year-old child into her home because the child was HIV positive, and her husband left her because he wouldn't be in that home. As she told her story, tears just streamed down my face. She looked in my face and said, "Elizabeth, I don't want to cry anymore." Then she broke into a deep, resonant song of hope that filled the room, and we all joined in, "Dumela, dumela", a song of hope. African grandmothers told us face to face as they hugged us how empowering it was to realize that women in Canada cared about them. Imagine their absolute delight if they knew that the Canadian government was going to step up and show evidence of its global care and compassion.

**The Chair:** Thank you.

**Ms. Elizabeth Rennie:** These are the stories. I have one more.

**The Chair:** Thank you, Madam Rennie.

**Ms. Elizabeth Rennie:** How can you not pass this bill? You have the power to save lives.

**The Chair:** I want to advise the committee that late last night an e-mail was received regarding a witness from Apotex—Bruce Clark. He is not here because of unforeseen circumstances. We will have his remarks submitted. They will be translated into both official languages and distributed to the committee.

Why don't we go to our technological link first?

Mr. Livingstone, please give us your opening remarks for five minutes, please.

**Mr. Angus Livingstone (Managing Director, University-Industry Liaison Office, University of British Columbia, As an Individual):** Thank you, Mr. Sweet.

I'd like to thank you for the opportunity to address the committee today. I'm the managing director of the UBC technology transfer office. I have about 20 years of experience in patenting and licensing university technologies, much of that in the biopharmaceutical sector. Over half of British Columbia's biopharma and biotech companies can trace their histories to UBC technologies.

At the outset, I'd like to acknowledge that I'm not speaking to you on behalf of the University of British Columbia—

**The Chair:** I'm sorry. Please move the mike closer, sir. We need to have a good, clear connection because of translation.

**Mr. Angus Livingstone:** That's as close as it comes.

At the outset, I'd like to acknowledge that I'm not speaking to you on behalf of the University of British Columbia but rather as a member of the university community, and the views expressed are my own.

I'm very proud to say that in 2007, UBC was the first Canadian university to publicly adopt the global access principles, which, stated briefly, make a commitment to making UBC technologies available to developing countries for health, environmental, and security purposes. This position was strengthened in 2009 as we worked with Yale and Harvard to develop the statement of principles and strategies for equitable dissemination of medical technologies.

To date, UBC has included a number of global access provisions in its licence agreements, including requirements for compulsory licensing, at-cost provision of medicines, and return of country of source. UBC and its affiliated hospitals conduct over half a billion dollars of research annually, and about 60% of that is in the life sciences.

My world has changed dramatically in the past five years, and technology licensing is increasingly difficult with the global distress of both the biotech and venture capital industries. Meanwhile, government is asking us to demonstrate a return on investment on the considerable funds that they have given us to conduct research.

It's in this difficult environment that I am seeking global access terms in my licence agreements, and it can be a very difficult sell. Drug development is an expensive and risky business without adding global access provisions that would only be implemented after drug approval some 10 or 15 years hence, when the world that we all know will look considerably different than it does today.

In reviewing Bill C-393 and the previous hearings, some things are clear to me. Everyone salutes the goal of making medicines available globally to those in need. There are many stars that must align, from the access to affordable drugs, to local infrastructure, medical personnel, water, sanitation, and other social determinants. While Bill C-393 may help alleviate the access to affordable drugs issue, in and of itself it is insufficient to ensure access to those in need. However, it does seem reasonable to remove the cost barrier in areas where they may exist, and such is the intent of Bill C-393.

Given the need for pediatric formulations, access to second-line drug regimes, and changing patent laws in India and China, the need to access patent medicines may arise more frequently.

My caution lies in the implementation and the potential unintended consequences as the pendulum swings from regulations that, by virtue of Apotex's Rwanda experience, have been seen to be cumbersome and unwieldy to the one-licence, all-country unlimited solution proposed by Bill C-393, which, in my opinion, lacks sufficient checks and balances.

In particular, I am troubled by the lack of country-by-country approval process and a licence bound by time. Couple this with the opportunity for countries to accept drugs not approved by Health Canada or the pre-qualified program of the WHO and there is potential for drugs without adequate safety or efficacy profiles to be in circulation. Removing requirements for specific marking, colouring, or labelling invites diversion opportunities both to other countries and also to other economic classes within the country of destination.

While diversion has not been a substantive issue to date, I know that 95% of the WHO's essential medicines are off patent and the incentive for diversion will increase with the costing control in the differential associated with patented drugs, which is the subject of Bill C-393.

Another legitimate concern expressed to me by companies in the first world market is the potential for first world market consequences of third world market adverse medical events. This could result in the regulatory halt of the drugs used in Canada and/or a substantive drop in market opportunities.

Finally, I think we need to consider the possible consequences of one major event related to either diversion or adverse medical events. This, in my belief, would reduce the R and D investment potentially funded by pharmaceuticals in Canada. That being the case, it could diminish our ability to develop drugs within the country and certainly my abilities to license them in the university environment. If that's the case, it could result in reduced access to medicines by Canadians.

● (1020)

Pharmaceutical development is a global business, and it's possible for industry to avoid jurisdictions that present unacceptable risks.

In summary, I support the revisions to the Canadian access to medicines regime to improve the efficiencies and effectiveness, but this must be balanced with adequate checks and balances to ensure that access is delivered in a controlled and accountable manner.

Thank you.

**The Chair:** Thank you very much, Mr. Livingstone.

Now we're on to Emilou MacLean for five minutes, please.

**Ms. Emilou MacLean (Director, United States of America, Campaign for Access to Essential Medicines, Doctors Without Borders):** Thank you. *Bonjour.* Good morning.

It is a pleasure and an honour to be here to testify. Médecins Sans Frontières is an international medical humanitarian organization working in over 65 countries, and I'm here to make primarily three points based on our experience.

First, quite simply, medicine saves lives in poor countries. It sounds quite basic, but it's important to say. Second, access to effective and affordable medicines depends on generic competition. Third, Canada can do more than it is currently doing to support access to medicines in developing countries.

The problem of access to medicines extends to any new drugs and to all diseases, yet AIDS continues to serve as a powerful example of both the dire needs and also the potential provided by price-reducing generic competition and, importantly, political will.

MSF began to provide AIDS treatment in 2001. At the time, a myriad of people said it was not possible in poor countries. There was insufficient infrastructure, it was said. Poor patients will not take their treatment regularly. Even, “Africans do not even have watches, how are they are going to know when to take their treatment?” At the time, there were only 8,000 people in all of Africa on antiretroviral therapy.

Now, of course, these arguments ring hollow. At MSF clinics we now enrol thousands a year rather than dozens. We are innovative, based on the resources available. Nurse-initiated treatment is common and effective. Treatment is radically decentralized and simplified away from hospitals and towards health posts, under trees, and on the roadside. To the skeptics, it is working. Some 5.2 million are on treatment who would not be alive without it, as apparently you heard in a previous hearing. A 2006 study published in JAMA found that Africans are on average more adherent than patients in North America to treatment.

The treatment scale-up over the past decade has only been possible as a result of generic competition. Generic competition caused annual first-line ARV drug prices to plummet from over $10,000 per patient per year to $67 per patient per year for the most affordable generic combination treatment today.

I was in South Africa working with MSF in 2002 when our goal was to provide treatment for 180 people in a pilot project. That first batch of patented drugs cost more than the car that drove the medicines from the pharmacy to the clinic. That may be fine for a pilot project to prove the skeptics wrong, to make a dent in the overwhelming need, and to be a call to action, but MSF could not provide AIDS treatment for 160,000, as we do today, at the price charged by brand-name manufacturers—nor could the global fund, to which the Canadian government just contributed $520 million U. S. over three years. Forgive me for doing the U.S. calculation.

PEPFAR, a major procurer of AIDS drugs, has likewise acknowledged the significance of generic competition in its global AIDS contributions. Initially resistant to the use of generic medicines, PEPFAR now procures—in a recent study published—90% of its AIDS medicines from generic manufacturers.

PEPFAR estimated that it saved $215 million U.S. in 2008 alone through the use of generic ARVs—$215 million U. S. In one year, PEPFAR's cost savings from generic procurement are more than one year of Canada's contribution to the global fund. That's not to praise the United States or to denigrate Canada, but simply to show the profound significance of generic competition in bringing costs down and making a scarce resource more affordable.

But times are changing. The dramatic reductions from generic competition are no longer available for newer medicines as a result of the TRIPS agreement intellectual property requirements. Second-line AIDS medicines, improved first-line drugs, and newer medicines for all kinds of other diseases are and will be more expensive, sometimes prohibitively so. Fixed-dose combinations—three-in-one pills necessary for good adherence and rapid scale-up—cannot be created if patented by different manufacturers.

In human terms, 10 million are in immediate need of first-line AIDS treatment. Drug prices matter dearly for these people. There is also an approaching treatment time bomb, a phrase recently coined by the U.K. Parliament's all-party parliamentary group on AIDS. Increasingly patients will need to switch to newer drugs for long-term survival, but the price difference is massive between the cheapest first-line medicines, more often available in generic form, and improved first-line, second-line, and salvage therapy, more often not.

For second-line treatment, the cost differential is a factor of seven. For salvage therapy or third-line, it's a factor of at least 23, where it's even available.

● (1025)

Drug costs will increasingly limit patient options and swallow health budgets without dramatic price reductions. AIDS is only an example, and it need not be the case. Compulsory licences provide a mechanism to allow for generic competition despite patent barriers. Compulsory licences on efavirenz led to a 50% price drop in Thailand and a 77% drop in Brazil, allowing the additional treatment of 20,000 patients in Thailand and a threefold increase in Brazil.

A workable paragraph 6 decision is critical for countries with no or insufficient generic manufacturing capacity, particularly as even least developed countries are obligated to adhere to TRIPS and enforce patents by 2016.

In Canada's first attempt to implement the paragraph 6 decision, or the August 30 decision, as it's sometimes called, it created additional unnecessary barriers for these most disadvantaged populations needing to use the system because they lacked domestic manufacturing capacity. Why should the poorest of the poor be triply burdened?

MSF invested years, ultimately unsuccessfully, as you heard this morning from Rachel Kiddell-Monroe, trying to use the system. There was clear need, but the burden on countries and generic manufacturers was so substantial and the delay so long that we secured a WHO pre-qualified Indian generic before CAMR could be made workable.

Notably, it was not a question of an inability to compete with the Indian supplier. Once produced, the Apotex fixed dose combination was $143 U.S. per patient per year, compared to $176 U.S. per patient per year from Aurobindo and Cipla in India. Canada could compete on price, but Canada hobbled because CAMR mandated slow speed and ineffectiveness.

If someone in Ottawa, Toronto, or Quebec acquires HIV, she can expect to live to about 70 years of age, according to recent studies. But what is available for those in developing countries living with HIV? At Médecins Sans Frontières, we urge Canada to support the easiest possible access to affordable medicines in developing countries with insufficient generic manufacturing capacity.

I lead into the industry representatives, and I'll say that the industry will always have excuses. I hope the government won't.

Thank you.

● (1030)

**The Chair:** Thank you, Madam MacLean.

Now on to Mr. Perry for five minutes.

**Mr. Grant Perry (Vice-President, Public Affairs/Reimbursement, GlaxoSmithKline Canada):** Thank you.

Honourable members, thank you for the opportunity to appear today to discuss GSK's experience with Canada's access to medicines regime and our company's extensive efforts, both globally and locally, to improve access to health care in the developing world.

There are three points I'd like to make. First, CAMR is efficient and effective at achieving its objectives. Second, the provision of medicines is only one essential element in addressing health care issues in the developing world. Third, GSK is committed through action to addressing access to medicines through frameworks like CAMR and other means. GSK's experience with CAMR has shown that it is an effective framework for Canada to meet its international obligations and for increasing developing world access to much needed medicines.

While 32 other countries in the EU and elsewhere have passed legislation similar to CAMR, to the best of our knowledge Canada is the only country from which a shipment has actually taken place. This first shipment of a triple combination HIV/AIDS drug to Rwanda from Apotex in Toronto took place in September of 2008.

First allow me to congratulate Apotex for stepping up to address the issue in Rwanda. The following chronology of events leading up to that shipment is important, because it demonstrates that only 68 days elapsed from the time Apotex made the request of GSK until they were granted authorization to begin exporting Zidovudine and Lamivudine to Rwanda. Please allow me to review this timeline with you.

You will recall that Bill C-9 came into effect in May of 2005, creating the Jean Chrétien Pledge to Africa Act, now called CAMR. Almost a full year passed before GSK and two other patent donors were approached by Apotex requesting voluntary licences. GSK responded promptly, indicating a willingness to discuss the granting of a licence and seeking clarification on key questions relating to anti-diversion and patient safety, both very real issues to GSK. Apotex did not respond at that time to our request for further information. Fourteen months later, GSK received another request from Apotex for a voluntary licence, and within 26 days we provided our consent to the commissioner of patents to issue an authorization pursuant to CAMR. Ultimately, one more year passed before the first shipment of a triple combination product was shipped from Apotex, not because of red tape, not because of a complex and lengthy process, but for reasons outside the administrative and legal process and not within the control of GSK. Apotex took more than one year to start shipping their generic drug to Rwanda.

Our experience is that CAMR can and does work when put to the test. In October 2009, GSK announced that it remains ready and willing to do our part within the framework of CAMR to ensure that the objectives are being met. We must not lose sight of the needs of patients in the developing world. While CAMR includes important safeguards and transparency requirements that help encourage R and D investment and support new drug discoveries, we must refrain from using CAMR as a means to re-open the intellectual property debate in Canada. While Canada lags behind other countries in IP protection, the protection afforded by Canada's rules holds the key to developing new medications that can fight and eventually eradicate many diseases that ravage the developing world. We must not become embroiled in an IP debate that would create further instability and drive away crucial investments in our country.

This brings me to our second point. The provision of medicines is only one essential element of many needed to address health care. As you've already learned from Ms. Downie and others, simply delivering medicines, whether brand or generic, doesn't nearly address the challenges developing countries face, such as poor sanitation and education, as well as social barriers. There are significant infrastructure issues related to the availability of health care workers, distribution networks, and health care facilities.

Finally, corruption and criminal activity can lead to diversion of medicines from the intended patients, either within the country itself or even before the medicines reach the national authority. We need a broader approach, one that goes beyond CAMR, and this is our third point.

GSK has long taken an innovative, responsible, and sustainable approach to improving the health of patients in the developing world. Working in partnership with governments, NGOs, and the private sector, GSK has among other things deliberately focused our R and D efforts on diseases of the developing world, such as HIV, TB, and malaria. We have sought to eliminate many diseases, including lymphatic filariasis, one of the world's most debilitating diseases, and we have consistently offered preferential pricing on antiretrovirals and vaccines.

This legacy of commitment is not enough. We have stopped saying it is not our fault there is no infrastructure to deliver health care and have started asking ourselves what else we can do to ensure that infrastructure does exist. Consequently, we have established several new initiatives that continue to address these broader issues and specifically advance GSK's leadership role. Specifically, we have recently begun sharing our intellectual property on neglected tropical diseases by setting up a patent pool and inviting others to join us.

● (1035)

We have opened the doors of our research centre, dedicated to diseases of the developing world, to all other researchers. We have reduced the price of our patented medicines in the least developed countries to no higher than 25% of what it is in the developed world, and we have committed to reinvest 20% of the profits made on medicines in these countries in local health care infrastructure projects. Finally, we have expanded the donation of albendazole to treat children at risk of intestinal worms, a condition that the World Health Organization's first report on neglected tropical diseases confirms causes more ill health in school-aged children than any other infection.

I am very proud to be part of the renewed partnership agreement between Canada's Research-Based Pharmaceutical Companies and Health Partners International of Canada to help speed the delivery of medicines and other supplies to people in need across the developing world.

In closing, we have illustrated that CAMR is only a piece of the larger puzzle, and that piece has proven to work effectively and efficiently when used. GSK's belief is that our collective efforts and intentions are best focused by serving the broader issue of improving health care in the developing world through leadership and action.

I thank you for your time, and I welcome any questions.

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

Now we'll move on to Mr. Williams and Mr. Dotto. I understand you're going to share your five minutes, so Mr. Williams, please begin.

[*Translation*]

**Mr. Russell Williams (President, Canada's Research-Based Pharmaceutical Companies (Rx & D)):** Thank you, honourable members. We are very pleased to join you today. I hope that we can contribute to the discussion and that the debate generated will be conducive to progress and innovation in access to medicines for developing countries.

I agree with the opinions shared today, but I think that these points of view are lacking a more practical side.

[*English*]

Canada's Research-Based Pharmaceutical Companies supports the principles of CAMR, but this regime is just one of the many partnerships and initiatives we have for fighting disease in the developing world. You heard about some of them today. You heard about others before, when CIDA officials appeared before you early in the fall.

There are many Canadian initiatives to help address health needs in developing countries. For our part, the Canadian member companies have collaborated with Health Partners International of Canada since 1990 and have delivered more than $250 million in donated medicines around the world. Globally, and I think this is very important, the innovative pharmaceutical industry is the third-largest funder of research and development on diseases in the developing world, behind the U.S. government and the Bill and Melinda Gates Foundation. Much remains to be done, but the evidence suggests that these voluntary efforts are paying off.

[*Translation*]

At the end of 2008, more than four million adults and children from low- and medium-income countries received antiretroviral treatment That's 10 times more people than just five years ago.

Sub-Saharan Africa, where the need is greatest, was the largest recipient. A similar improvement was noted in the delivery of drugs to pregnant women to prevent the transmission of AIDS to fetuses.

[*English*]

CAMR has worked when the rules have been followed, but there are several provisions in the bill before us that concern us.

First, the current obligation to seek voluntary licence within CAMR would be repealed.

Second, the existing country notification on the limits of product quantities would be repealed.

Third, the bill would make a licence open-ended, even if the circumstances that led to it no longer existed.

Fourth, the bill would allow medicines to be exported from Canada to developing countries without Health Canada's safety approval. This would create a double standard with respect to the safety of medicines used in this country and the medicines sent abroad for humanitarian purposes.

Finally, there is the potential for diversion to other countries. The global corruption report identifies procurement, distribution, and counterfeit medicines as sources of corruption in pharmaceutical supply. The WHO reports that one out of four medicines in developing countries is counterfeit. In particular, we would ask what purpose is served by renewing the ability to terminate a licence if the humanitarian products are found to be re-exported from a country where they were originally sent. That is a straightforward question.

What concerns me most is the amount of time and effort that has been focused on this bill, when with the collective energy and unanimity I'm hearing about with respect to trying to make Canada do more, we could focus more on some of the voluntary infrastructure programs and the partnerships the industry has been making, and it would be more successful.

[*Translation*]

I will now yield the floor to Mr. Dotto, of Abbott Laboratories.

● (1040)

**Mr. Laurence Dotto (Director, Government and External Affairs, Canada's Research-Based Pharmaceutical Companies (Rx & D)):** Thank you.

I'm very happy to be here today. I have been volunteering in Africa for eight years through our family-focused charity that provides assistance to women and children in Malawi. So far, we have successfully completed more than 15 local sustainable development projects, which were mostly health-oriented.

When I first visited Malawi, in 2003, access to HIV testing was extremely limited. Companies like Abbott provided free screening tests, but administering those tests was always an issue.

[*English*]

Today, fortunately, testing is much more widespread. There are HIV treatment programs in rural areas, and most small hospitals have now set up HIV programs with trained volunteer counsellors, paid counsellors, and are receiving antiretroviral drugs through several NGOs.

Today, the drug supply issue has essentially been solved in many of these countries. Generic HIV drugs are starting to stream in from India and South Africa. Hospitals today are receiving free HIV drugs and free antimalarial drugs through these NGO government partnerships.

In my view, the biggest challenge facing countries like Malawi today is a continuing absence of health care infrastructure. There's only one doctor for 50,000 Malawians and one nurse for 20,000 people. As well intentioned as Bill C-393 may be, it does not address the real challenges, the core issues of poverty, education, nutrition, and access to basic health care faced by less developed countries.

In my view, if Canada were to make a serious contribution to the fight against HIV/AIDS in Africa, here are a few priorities to consider: greater support for prevention of mother-to-child transmission counsellors who go from village to village and counsel and test pregnant mothers; more mobile health clinics to travel to the villages; and how about transportation funds to allow an HIV-positive mother to take that minibus to an ARV clinic that's two days' walk away from where she lives?

Programs to identify HIV-positive children are urgently needed so they can find their way to a treatment program. With 80,000 HIV-positive children in Malawi and only a few hundred in Canada, what could be more important than trying to support the Malawi of tomorrow?

In my view, these are the real needs and these are the practical ways to build a more effective health care infrastructure in countries like Malawi.

**The Chair:** Now we'll go to rounds of questioning. I'll just remind members, as well as witnesses, to try to keep your questions succinct and your answers succinct to get the most value out of this.

For five minutes, Mr. Garneau.

**Mr. Marc Garneau:** Thank you, Mr. Chair.

I want to begin by saying to Mrs. Rennie that her testimonial was very moving, and the part I remember the most was her comment that this can only be solved if we increase the supply of medicines to those who need them.

I've had the pleasure of having the Grandmothers for Africa twice in my office during the past year. I had two grandmothers, so I know how powerful grandmothers can be. I want to say again, with respect to the intent, I share that intent 100% to get those medicines to those who need them.

I'm an engineer. I think in very Cartesian terms, and I'm saying to myself, some people are saying that CAMR doesn't work as written and we need Bill C-393. Other people say it does work and we don't really need to focus on that, but rather we should be focusing on all of the other challenges with respect to infrastructure and other matters, which I think you probably agree with, that all those other things also need to be addressed.

But as part of my trying to understand this argument, it's very difficult for me to understand who is right, because the positions are diametrically opposite in many ways. I dearly wish that Apotex had been here this morning. It's very unfortunate they're not here, because I had some definite questions to ask them.

Given that they're not here, I'm going to ask my questions to Mr. Perry and Mr. Williams, and I'm coming back to this issue. Under current CAMR rules there's been one case, the Rwanda case, and Apotex was involved. I want to hear again, because this timeline is really confusing me. It was 68 days that was supposedly required for the three providers of patent medicine to grant a voluntary licence to Apotex. Then it took a year for the medicines—supposedly 15 million pills were authorized—for the first batch to get there, and then another year for the second batch.

I'm trying to understand why, when it appears that the process worked well in terms of granting of the voluntary licence, it took a year to get the medicines over there. I'd like to understand that a little bit better, so I'd like to hear your interpretation. I wanted to ask this question of Apotex, but they're not here. I'd like to ask Mr. Perry and Mr. Williams what their view is of that.

Mrs. Rennie and Mrs. MacLean, I'd be glad to hear your views too.

● (1045)

**Mr. Grant Perry:** With respect to why it took Apotex a further year after the authorization or licence, you'll have to ask Apotex that; unfortunately, I'm not in a position.

I can say that within three weeks of the original request, we responded to them to say that we were willing to discuss a voluntary licence, but we did not hear back from them. Three months later, we rewrote them saying that we had not heard from our original request and asking whether they wanted to speak with us. It took until July of the next year—from the previous September—to get yet another request, and 26 days later we told the commissioner of patents that we were willing to abide by the rules of CAMR and allow for authorization of our product.

As to why it then it took a year after that, unfortunately I'm not in a position to respond.

**Mr. Russell Williams:** There's been speculation that it's price negotiations, etc., but we don't know that. What we can clearly say, and we have all the dates documented and have submitted the documentation to the Senate committee, is that it took 68 days of CAMR. All the delays, whatever the causes were, are not about the bill we're talking about.

**Mr. Marc Garneau:** Ms. MacLean.

**Ms. Emilou MacLean:** I would largely rest on the comments made by Rachel Kiddell-Monroe in the earlier testimony, because she was the key person based in Canada who was working on this within MSF. But the biggest burden from our side came earlier; that was trying to get a country to come forward and commit to be part of this, given the pressure that countries face when they attempt to use compulsory licences, both from industry and from developed-country governments who are resistant to the use of compulsory licences.

**Mr. Marc Garneau:** That's a generic comment. I want to know why it took a year in this case.

**Ms. Emilou MacLean:** I'm going to rest on the comments that were made by Rachel Kiddell-Monroe earlier on this, because we were not involved in the actual purchase of the Apotex—

**Mr. Marc Garneau:** That's what I need to find out; that's my problem.

Mr. Livingstone, you've had an involvement through UBC with the kind of issue we're talking about today. I'd like to ask you, what in your opinion is the most fragile part in this chain, based on your experience, when trying to provide life-saving drugs to those who need them in third-world countries? What is the most fragile part in that chain? We've heard about infrastructure that's lacking and about other things. I'd be interested in and would like to hear your viewpoint based on your experience at UBC with your colleagues, because I know you focus on this. That certainly is something that we in the Canadian Parliament should be focusing on as well.

**The Chair:** Be as brief as possible, Mr. Livingstone.

**Mr. Angus Livingstone:** I think I would describe it, rather than as a chain, more as a network. In the case of access to medicines, it clearly has to be there, but whether sourced through patented drugs or through generics, there are multiple ways of getting access to medicines at affordable prices, and one or the other has to be there. There will clearly be issues in delivery within Africa, and the infrastructure and educational problems are critical as well.

So I don't think there is a "most fragile" part; in many cases, there are very viable alternatives that can be sought.

● (1050)

**The Chair:** Thank you, Mr. Garneau and Mr. Livingstone.

[*Translation*]

We now go to the Bloc Québécois.

Mr. Malo, you have five minutes.

**Mr. Luc Malo:** Thank you very much, Mr. Chair.

I want to thank all our witnesses for assisting us in our study of this bill.

Like Mr. Garneau, I am somewhat disappointed that the Apotex representatives are not here. We are very concerned about how long it took to deliver the medicines. We were told that it took far too long, but Mr. Dearden was not of the same opinion. Public officials who appeared before the committee at the beginning of the study agreed with him. Mr. Perry told us that his company handled everything promptly. We're really wondering what all that time was wasted on. That's why it would have been interesting to hear what Apotex representatives have to say about this.

Ms. MacLean, I'd like you to clarify some of your comments. You said that first-line generic medicines could be supplied at low cost because companies were competitive. So, first-line medicines are available at a lower cost. We need the same level of competition for second- and third-line medicines.

I'm just wondering how amendments to the current regime will help create more competition if Canada is the only country making such changes.

[*English*]

**Ms. Emilou MacLean:** As has been said, Canada and CAMR are not the only solution to all of these problems. Canada needs to be a player, and Canada has taken a leadership role. There's a lot of mobilization. We've seen all the grandmothers who are here today; we've seen a number of other political actors who have come forward to say that this is a priority; we've seen two hearings in the last week on this, as well as a number of hearings that have taken place before. There is a lot of momentum here that does not exist in other countries.

Canada is in a position to really take on a leadership role, demonstrate what can be done, demonstrate what the most effective language would look like in a paragraph 6 decision or an August 30 decision that could work. There is a critical need, and an increasingly critical need, as India's generic market is under threat because of TRIPS, as all least-developed countries are going to need to implement a TRIPS-compliant intellectual property regime within the next five years.

So Canada is in a position to take a very strong leadership role. It's not the only solution, and other countries hopefully would come forward as well. But there is a real need, and Canada can be a real player in this.

I hope that answers your question.

[*Translation*]

**Mr. Luc Malo:** It doesn't, but your answer is very interesting. We must build on the momentum to ensure that more medicines become available. I understand that very well.

However, my question was about your comments. You said that for a drug to be available at a lower cost, we need competition among companies, since competition would drive down costs. If only Canada amends its regime, how will that create more competition in the second-line medicine market?

[*English*]

**Ms. Emilou MacLean:** I understand the question perfectly now. Thank you for the clarification.

One of the key components of the competition is the generic competition as compared with the originator drug. That is already competition. If Canada is producing a second-line drug that is not available in generic form elsewhere, which may be true when India's generic market is under threat, and if other countries are not actually producing generic drugs, because all countries with generic manufacturing capacity are now obligated to adhere to the TRIPS regime, there are very limited, and increasingly limited, options. So the inclusion of any additional generic competitors into the market, especially the market for newer drugs—second-line drugs, third-line drugs, or new and improved first-line drugs.... There's already competition to the originator drug, which does not exist. That's why we see the very expensive drugs now, as compared with the first-line regimen.

Does that answer your question?

● (1055)

[*Translation*]

**Mr. Luc Malo:** You're getting a little closer.

[*English*]

**Ms. Emilou MacLean:** Please, feel free.

[*Translation*]

**Mr. Luc Malo:** I'll ask you another question, since I know that Doctors Without Borders is present in many countries that, like Canada, would likely allow medicines to be supplied. I'll talk about second-line medicines, such as second-line antiretrovirals.

Would it be possible, through various agreements, to help open the market to competition, not only here, but throughout the world? Does Doctors Without Borders notice such problems in the rest of the world?

[*English*]

**Ms. Emilou MacLean:** I'm not sure whether it's a problem in translation, and I apologize that my French is not better, but I don't quite understand what you're saying. What agreements do you mean? Where the market is opened up? Are you speaking about and thinking about the free trade agreements, or are you thinking about something else?

I apologize if it's the language and the translation; I apologize to the translators.

[*Translation*]

**Mr. Luc Malo:** My question was perhaps a little too vague. I will be more specific.

Mr. Attaran, among others, said that a number of countries have regimes that are similar to Canada's Access to Medicines Regime. However, abroad, there were no medicines available. There were not even first-line medicines. There were simply no medicines available.

Is that because there are too many international barriers, or perhaps because there is no genuine goodwill when it comes to access to medications? I would like to know what Doctors Without Borders thinks about this.

[*English*]

**The Chair:** Be as brief as possible. We went way over for that clarification.

**Ms. Emilou MacLean:** Yes.

Canada's is one of the more developed mechanisms, and the work that's happening right now demonstrates how this ends up being developed. There have been many conversations about what this would actually look like; there's been a lot of engagement in this process. Some other countries, while they may have something that looks like implementing legislation, don't necessarily have implementing legislation that is workable or that is defined enough to be able to move forward.

Then I would go back to the question of political will. There is an enormous amount of political will, as demonstrated by all of us who are here today and the thousands of postcards that are here and the many others who have spoken out on this issue, all of which has pushed this forward in Canada in a way that it has not been pushed forward in other countries.

[*Translation*]

**The Chair:** Thank you, Mr. Malo and Ms. MacLean.

[*English*]

Now on to Mr. Brown for five minutes.

**Mr. Gordon Brown (Leeds—Grenville, CPC):** Thank you very much, Mr. Chairman.

And thank you to our witnesses today. I think this is something that all Canadians care about.

Mrs. Rennie, you said that Canadians care. I would go as far as saying you'd be hard pressed to find a Canadian who didn't care, and you'd probably be hard pressed to find a Canadian who wouldn't sign one of those postcards and send it in. I want to congratulate you on all your efforts in pushing this important issue.

Mrs. Rennie, you did say there were other things that could be done to help. Just quickly, could you tell us a few things that are on the top of your mind in that area?

**Ms. Elizabeth Rennie:** When I was in Africa, I saw evidence that the Africans are building their own infrastructure. I visited a number of projects where the women were in fact rebuilding their communities. I find it a bit patronizing for us to assume we should tell Africans how to build their infrastructure. But I think we need to give them the support, and the support means being alive. We can talk about all the infrastructure we want, but if people are not alive to work, then all the infrastructure in the world doesn't make any difference.

I'm not sure, Mr. Brown, whether I'm answering your question.

**Mr. Gordon Brown:** No, but that's okay. Thank you very much.

Mr. Chairman, I, along with other members of the committee, am very disappointed we're not going to hear from Apotex. I have a lot of questions for them. We've heard a lot from witnesses over the last number of weeks about how CAMR has worked or hasn't worked, and they have been the only company that actually has used it.

Maybe some of our other folks—Mr. Perry, Mr. Williams, and Mr. Dotto—could help. They have had the opportunity to work a little bit with them.

How has Rx and D worked with generic companies to implement some of the goals of CAMR? Because Apotex isn't here, maybe you can help us with this.

● (1100)

**Mr. Russell Williams:** Absolutely. I think some of the criticisms about CAMR would be a little more credible if there had been a second application, or a third application, and it hadn't worked. At least Apotex moved forward on the first one, and that should be duly noted. Where has everybody else been?

I think what you're seeing on the international level is a movement towards more and more.... I think this is why this debate about compulsory versus voluntary is confusing. The action and the partnerships are actually being developed around the world—generics included, with us—on a voluntary basis. It gets very creative. It gets into some of those programs that the grandmothers have been talking about. It gets into infrastructure. It gets much more creative.

I think we're getting pulled into an IP debate when we're actually talking about humanitarian issues. We can be much more creative with that voluntary effort, and I think the two companies can talk about specific examples.

We get into investing in research and development. We get into community involvements around the world. Sometimes we do it in partnerships. There is the Canadian example of Health Partners International. We actually donate products with them, along with the generics. There are exercises we can do together, versus just focusing on rewriting CAMR.

I don't know if the two others would like to add examples.

**Mr. Grant Perry:** As we've already discussed, the one attempt by Apotex to discuss a voluntary licence, which we're willing to undertake with them, did not come to fruition.

Our main activity is global. We do a number of different things in terms of trying to meet the needs, and I think I've touched on some of them. We have voluntary licences with eight manufacturers in sub-Saharan Africa alone. Those eight manufacturers delivered 270 million tablets of antiretrovirals into sub-Saharan Africa.

You compare that to the 15 million tablets out of Rwanda, and that's just GSK. I know Pfizer, Abbott...every other company has their own way of moving forward and specifically working with generics.

That's just one piece we do, whether it's not-for-profit pricing, partnerships with the Gates Foundation and the like, partnerships with other parts of the UN.

That's one specific around generics globally.

**Mr. Gordon Brown:** Other than Apotex, have there been any other generic companies that have indicated any interest in using CAMR?

**Mr. Grant Perry:** None. Not that we're aware of.

**Mr. Gordon Brown:** All right.

**The Chair:** Mr. Brown, it's your time we're using, but Madam Watson has had her hand up, if you wouldn't mind.

**Mr. Gordon Brown:** I was just about to go to her.

Go ahead.

**Ms. Linda Watson:** Thank you, Mr. Brown.

**Mr. Gordon Brown:** I'm not sure which question you wanted to answer, though.

**Ms. Linda Watson:** I'd like to answer them all, but I will start by saying that I don't believe, with all due respect, that voluntary donations are an answer. Mr. Williams has quoted that something like $235 million worth of product has been donated by brand-name pharmaceuticals since 1990. When you divide that by the number of years and the number of companies, that's $265,000 a year. That does not substantially address any issue in the southern world.

Second, preferential pricing would still only bring prices down to one-quarter of the price in the developed world, whereas generic competition has dropped the prices 17 times over against brand-name prices. The generics have to be part of the picture. It's not an option. That's where the action is. That's what's saving lives right now.

Also I just have to take issue with some of the comments. I believe it was Mr. Williams who said that he regretted that time was being wasted on Bill C-393 when we could be spending our time more fruitfully coming up with answers to some of the other kinds of issues of infrastructure and sanitation and all those sorts of things. I believe the House of Commons is the body that decided Bill C-393 was deserving of the attention of this committee, and we are doing House of Commons business, the business of Canadians, and it's right that we do it well.

**The Chair:** Thank you, Madam Watson.

Mr. Williams, go ahead, very briefly.

**Mr. Russell Williams:** Just very briefly, what we said was that we are voluntarily collaborating internationally, and absolutely with generics, and that has proven to be far more effective. That partnership is the solution, but it's voluntary. We're very proud of the donations we make and we've made them on a voluntary basis. But never did we suggest that's enough.

I was trying to make the point that CAMR is limited and goes only so far. What we thankfully have been seeing—and I hope we can continue to work with everybody on this—is that if we push the voluntary collaboration, not for donations but for partnerships, we can go much further and respond to it, and I actually think we all unanimously agree on this issue.

● (1105)

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

Sorry. Time always marches on for us, and I just want to be fair to every member and every witness.

Mr. Masse, go ahead for five minutes, please.

**Mr. Brian Masse:** Thank you, Mr. Chair.

I would ask that maybe the research providing the testimony from Apotex, which was provided in the Senate with regard to Bill S-232—because they did answer on that—be distributed. That may be the next best thing we can get, because it is official, on-the-record testimony under the same rules as that of the House Commons.

Ms. MacLean, you made me smile when you talked about the watch, because that was one of the things we were told. I've heard these condescending arguments about “oh your intent is good”, and “if you just understood things a little bit better....” It diverts people from the real issue, which is that Parliament decided there was a role for the private sector to play with regard to this human catastrophe we have across the globe. We, as the public sector, could continue to do, and should do, some other things, such as what Mr. Williams was suggesting, and as common global citizens we could use public sector money to build that infrastructure. But the legislation is set up with the intent, and to recognize, that the members of the private sector, especially given the fact that they get generous research and development and a series of other tax breaks, could actually expand the usage of those terrific breakthroughs. We thank them for the work they're doing, and as long as that information was protected and respected, we would develop a system to expand the use of patents across the globe.

Mr. Perry, we've had only one case so far with Apotex. Say, for example, Bill C-393 went through and we had five per year that were granted from there on. I'm speaking hypothetically. Would that drive away investment from your company, from Canada, because the usage of that went further?

**Mr. Grant Perry:** I think the same question was asked of the officials earlier this week. Maybe I could look at it from one side and then come back to your question.

But if you look at Bill C-22 and Bill C-91, which were about the restoration of patent protection for the innovative pharmaceutical industry to the same industry standards as every other industry in the country, we actually saw the fastest growth rate in R and D in the developed world. So we went from about $40 million a year to well in excess of $1 billion a year, showing that actually providing patent protection can attract investment.

Whether the specific of five coming through or three coming through will lead to a reduction in R and D, the challenge we face is the instability caused by uncertain IP protection. It does have impacts on our ability to track that investment globally.

**Mr. Brian Masse:** Let's get this straight, though. If there was going to be some illegal activity by a generic in this situation and we hit that really hard, the commitment is there to go.... Are you suggesting...? It has been out there. The department is saying it, and they can't say where it's coming from, that investment would dry up and billions of dollars would be lost.

I want to know, if we protect those patents, if we respect those patents, if we make sure they're done properly and the drugs go to the places where they're clearly on the mark and they're identified and they're evolved, you're going to pull back investment if more people get treatments for HIV, tuberculosis, malaria? We want to protect that IP. We just want to build the work better. We want the generics and more drugs to get out there.

If that happens, are you going to pull back investment?

**Mr. Grant Perry:** First of all, I think the evidence in our mind is that we don't have evidence that the bill doesn't work. As we've said, we've had one.

Secondly, our concerns are that the bill does not actually protect our intellectual property. It does not do the things you were saying in fact we should be doing. That's our concern.

**Mr. Brian Masse:** And that's fair. But say that we pass the bill, we make some amendments and make this more accessible, and then if we do have a problem, sure, we'll get right back and fix it again to stop those illegal or unintended consequences that none of us wants. Wouldn't that satisfy you and your company that you're going to get that type of protection? If we do make changes so that it can get used more and then it comes back in our face some way, or whatever—I don't think it's going to happen, but if it does—and you have our word that we will fix it again right away, is that not good enough?

**Mr. Russell Williams:** Can I jump in here, Mr. Masse, if it's all right?

**Mr. Brian Masse:** That's okay, yes, of course, Mr. Williams.

**Mr. Russell Williams:** This presumes that IP is a barrier and you're presuming that weakening IP in this country is going to facilitate access to medicines. I don't believe that. I think what we have to work very carefully on here is that unintended consequences could be quite serious. I identified some of them in my remarks, and I think we should be very careful. You heard other testimonials that 95% of the WHO medicines aren't patented. We could achieve what you're trying to achieve but through a more creative, voluntary way.

● (1110)

**Mr. Brian Masse:** You say it's weakening IP. I say it's sharing IP and protecting that share of the IP.

**Mr. Russell Williams:** Then why haven't more people come forward?

**Mr. Brian Masse:** The reason is we built a broken law and we knew it.

**Mr. Russell Williams:** It worked.

**Mr. Brian Masse:** We built a broken law that has been modelled after other countries and we knew it, and that's the choice we have to make. We have to choose whether we want—

**Mr. Russell Williams:** When the rules were followed it worked.

**Mr. Brian Masse:** —to change the law, to be involved.

I'll ask Mrs. MacLean to answer that.

**Mr. Russell Williams:** But when the rules were followed it worked in 60 days. Thank you.

**The Chair:** Madam MacLean, as briefly as you can.

**Ms. Emilou MacLean:** Okay. Just one quick point about how the rules did not work, which I think responds a little bit to the question you had raised earlier, Mr. Garneau, and it is related to this as well. It's providing information by Rachel Kiddell-Monroe, who's involved in this. We couldn't actually go forward with our process without a named country, and that was a real barrier, so that was an error in the process that did not work. I think the pharmaceutical industry perspective on this is that patents are not a barrier because there are voluntary mechanisms that can be used.

I just wanted to respond to that and say that voluntary mechanisms generally are not voluntary entirely. They usually exist because of pressure either from litigation or from the threat of a compulsory licence. There's certainly value to the threat of a compulsory licence, and there were a number of different examples of this, such as in South Africa when there was a competition commission challenge and in India when there was pre-grant patent opposition. Those are when voluntary licences get issued and when these collaborations exist.

**The Chair:** Thank you, Madam MacLean.

Now on to Mr. Rota for five minutes.

**Mr. Anthony Rota:** Thank you, Mr. Chair, and again thank you to all the witnesses for being here today.

I have a question for Mr. Perry. You made a statement, and I'm trying to work this through and I'm having a hard time with it. You mentioned that CAMR—I think it was in your statement—was successful. One shipment in six years...no one else is interested. Can you define success to me, because I'm having a hard time?

**Mr. Grant Perry:** CAMR was successful in that the one time a generic company tried to use the mechanism, it worked in less than 70 days. We have not had failures. We have not had a number of generic companies try to use the program and not be able to use it.

I can't determine when the generics will choose to use it or not to use it. Is it a question that there's not a need for it? Is it a question that there's a safety valve that exists to meet needs where they aren't being met through other programs internationally? I can't answer for their choices for not using it, but when used, it worked.

**Mr. Anthony Rota:** So it looks good on the shelf—

**Mr. Russell Williams:** I'm perplexed that they're holding off. I am very perplexed. The generic companies are sitting back and telling Canada that unless parliamentarians change this law, they will not use it again. I find that kind of positioning, when we're talking about this kind of humanitarian cause, quite—I'll be careful with my words—inappropriate. I find it inappropriate that we should be pushing ourselves to push harder and apply and make sure this law works. I find it astounding that the companies are sitting back and telling politicians that they're not going to apply until you change the law.

**Mr. Anthony Rota:** When we put laws together, I look at something...like, how functional is it? If it just sits on your shelf—it makes us feel good but it doesn't work, and nobody's using it—then the law isn't functional.

I'm trying to make heads or tails out of this, and it comes down to IP, licensing...?

Ms. MacLean, did you have a comment you wanted to make on this?

**Ms. Emilou MacLean:** I would just say that in the conversations we have....

I guess I'll start back at the beginning. Normally when we're purchasing drugs, we make an order and we get the drugs. There aren't many other steps in that process. When you have to go through the CAMR process, there are about 30 other steps in that process. There is a stunning diagram that demonstrates what that comparison is.

Countries have told us, "We don't even understand the legislation, so how can we go forward with this?" There are enormous barriers in there. I mean, we can speak about what Apotex would say. We know from the other side that there is another initiation of that process that has to happen also from the countries' perspective. The countries are not going to move forward with it. They're not here to testify. They weren't invited to testify. No criticism to the committee, but Apotex is not here, and was unavailable today.

The countries' perspective, as they told it to us and as they experienced it with us, was this: the system was unworkable and it needed to be changed.

**Mr. Anthony Rota:** Okay.

I'd like to go back to the one-licence solution. I'm not going to say it's a cure-all, but it seems to be something that would allow drugs to get out there. It would make it worthwhile for the companies.

Mr. Williams or Mr. Perry, how would this affect your companies?

**Mr. Russell Williams:** I think you have seen already, in the one example that's been effective, that when there were terminations of time schedules, the three companies involved on our side voluntarily extended them and supported the principles of CAMR. That was a non-issue. It seems to me that the checks and balances that parliamentarians unanimously put into CAMR are actually there, and they work. Once they go through it, and people have some dialogue.... To my understanding, the renewal was done within a week.

Again, I'm having a hard time buying that there are problems here if people actually want to work this out together.

● (1115)

**Mr. Anthony Rota:** You're okay with that, Mr. Perry?

**Mr. Grant Perry:** Yes.

**Mr. Anthony Rota:** Okay.

I'm going to switch over to something else, something that comes up often, and that's that the infrastructure is non-existent. It's the chicken and the egg: which one comes first?

Mr. Dotto, you were talking about how hospitals are in place in rural areas, and Ms. MacLean, I'm sure you've had a lot of experience. Maybe from the two of you—I believe I'm running probably fairly short on time, so I'll open the question to both of you—how did you see the hospitals develop, and why are they not developing sooner? Does the medication stop or does it help them?

I mean, if we have something that we can use, we want to develop the infrastructure. If we don't have it, we kind of give up hope and walk away. That would be my way of looking at it, or my interpretation of it, but I'll leave that open to the two of you to comment. Maybe just explain to me, first, how infrastructure develops, and second, whether more medication going into a country would help develop that infrastructure.

**The Chair:** Madam MacLean first, as briefly as you can, then Mr. Dotto.

**Ms. Emilou MacLean:** I'll be as brief as I can.

I would like to give a specific example of a colleague of mine who was working to start an antiretroviral treatment program with MSF in the early days in Mozambique. His wife, a gynecologist who was working on maternal mortality, said, “We don't even get support to be able to do work on maternal mortality. How do you expect to be able to roll out antiretroviral treatment when there are all these burdens and all these barriers and all these arguments about this not working?” And he said, “We're changing the paradigm. There's been recognition of a stunning disease devastating the global south, and we're going to bring that to the fore and change the paradigm.”

We have seen that infrastructure gets built and resources come forward; when there is political will, you can actually respond. Some 5.2 million people who are on treatment today would have died without it. There were 8,000 people on treatment in all of Africa a decade ago.

So the arguments about infrastructure made at that time—they're the exact same arguments that are being made about infrastructure today.

**The Chair:** Mr. Dotto.

**Mr. Laurence Dotto:** I would just add in terms of infrastructure that I think it's a critical issue. Many times the infrastructure will only change when there is support from partnerships—partnerships with governments, partnerships with NGOs, partnerships with companies like Abbott, Glaxo, and others.

In the countries where you are starting to see significant changes in infrastructure capacity.... Take Malawi, for example, where the HIV rate six years ago was running 13% to 15%. Through a lot of collaboration partnerships, that HIV rate now is down to 12%. They've dropped several points. So in order for that type of thing to happen, I think these are the sorts of partnerships and collaborations that are needed.

In terms of getting access to the medication, six, seven, eight years ago, this was a huge issue, but today many of these countries have moved on. They're now getting source drugs from countries that they weren't six years ago.

I think that's another reason why you're not seeing people asking from Africa. I'm not sure how many people here today are here representing the African community, but I think you have to ask yourselves, “Why are they not here? Why are they not asking for these medications?”

**The Chair:** Madam Watson, you have 30 seconds.

**Ms. Linda Watson:** Oh, Mr. Sweet.

I want to say that we grandmothers are aware of a different paradigm of infrastructure in Africa. There are places like the Hillcrest AIDS Centre, where there are only six registered nurses, but a whole army of volunteers have been trained to do home-based care and take medicines where they're needed. There is the situation of the Consol Homes in Malawi. One couple went around to try to get help for 63 orphans. They now have 107 centres, over 500 volunteers, and are treating 30,000 African children and getting them medicines. There is an infrastructure that's working now. The people there care enough to put their feet down and make it work.

I want to know that this country cares enough to do its part to make this legislation as effective as possible. I am very distressed, and even outraged, by the rumours we have heard that the decision of this committee was made before these hearings even began, and that when the report comes back this bill will be dismissed on a procedural technicality. That is an insult to this committee and an insult to the champions of this bill.

I ask you, Mr. Sweet, to please guarantee that your clause-by-clause deliberations will be conducted with full account of the merits of this bill and the hearings you've heard, and that members of this committee, at least, are not complicit in trying to dodge the transfer of sponsorship to Mr. Masse when it comes to the House.

● (1120)

**The Chair:** Thank you, Madam Watson.

We'll go to Mr. Lake for five minutes, please.

**Mr. Mike Lake:** I'm going to make a few comments, and then I will direct a question to Ms. Watson and Ms. Rennie.

I want to start by saying that there are a lot of grandmothers here in the room, and in my five years as a parliamentarian I have not met a more compelling or motivated group of witnesses on any issue.

I can assure you that the first question I had when I saw this piece of legislation come before us and I sat with officials to talk about it was whether there was any way at all to modify this bill to achieve something positive, without the negative unintended consequences we've talked about. As far as addressing this issue, we're on the same page.

Ms. Rennie, in your opening statement you said that we need to do something. I think we can all agree that we need to do something.

There are a few other things you talked about in your opening statement. You said the issue is not about patents or intellectual property; it's about people. Part of the problem in dealing with this bill is that while I agree with you that the issue is about people, the bill is entirely about patents, IP, and food and drug regulations. That's where we're going to see unintended consequences. It's our job as parliamentarians to consider the impacts of the legislation we pass on all sorts of things.

You also talked about the need of the Canadian government to step up. We've heard that from witnesses who have come before the committee in the past week. We heard it today when Ms. MacLean talked about the 5.2 million people who are getting treatment today. I think you said there were 8,000 originally. The numbers we have are 400,000 in 2003, and I believe there was a twelve-fold increase to 2010 to get to 5.2 million. It seems that we're well on our way to the 10 million in total that we need to get to.

I would say that something is working. We know that considerable momentum is occurring. We can see that through the investments we've made in the global fund—$540 million for the next three years—a significant contribution is being made by the Canadian government. Let's face it, that contribution is simply being made by Canadians. We're not spending government money, we're spending taxpayers' money, Canadians' money, and we've increased the amount we're spending. So we're seeing some impact.

I have to be honest with you, Ms. Watson. You made some comments about what's going to happen with this bill. I voted against it in the first place when it was before the House, for what I consider to be good reasons. At this point I haven't heard anything that convinces me to not vote against it the second time. But I want to assure you that moving forward I want to focus my attention on addressing the actual issue: that people in Africa who don't need to be dying are dying for want of very simple solutions. We need to find ways to address that.

As we move forward, if this bill doesn't pass, how can we take the momentum and considerable enthusiasm the grandmothers bring to the table and work together to achieve some real results? What other areas could the grandmothers be working on, or are working on currently?

**Ms. Elizabeth Rennie:** Thank you, Mr. Lake.

Obviously, some things are working. On the other hand, there are still millions who are dying. As we've said, this is but one solution. I don't know how many times people have to hear from the experts about the intellectual properties being compliant with this bill. I don't know how many times we have to say that and hear that from the experts. I don't know how many times we have to say that the existing CAMR includes a clause about diversion. Diversion is not a problem. I think this is constantly sidetracking us from the real issues of how to make this work.

I can speak for myself; I'll speak for thousands of others: of course we want to make it work, and we will work with anyone who is going to offer a viable solution. We think we have a viable solution with this. What can we lose, Mr. Lake, by trying it? What can we lose?

● (1125)

**Mr. Mike Lake:** The answer is that there are significant unintended consequences, and of course the experts that came before us from all four departments, experts who are not partisan, who are the people we rely on to give professional advice on these issues—

**Voices:** Oh, oh.

**Mr. Mike Lake:** No, for clarification, they are people who would be there regardless of who's in government, giving advice on these issues from all four departments involved. They have advised very strongly against unintended consequences of this bill.

**Ms. Elizabeth Rennie:** We're not paid lobbyists. We really are multi-partisan.

**Mr. Mike Lake:** These are departmental officials I'm talking about. I'm not talking about anybody else who has come before the committee. I'm talking about the departmental officials, our professional public service, simply for clarification.

**Ms. Linda Watson:** Mr. Lake, to your question about what other sorts of things grandmothers would support to see change and improvement in the lives of those who live in sub-Saharan Africa, particularly the grandmothers and the children orphaned by AIDS in their care, we would like to champion seeing Canada on a timeline to reach the 0.7% commitment to official development assistance, relative to GNI, that we committed to back in 1970 and have recommitted to many times. We would like to see Canada increase its contribution to the global fund, to its true fair share, in fact.

But we are dealing with this bill today, having discussions about infrastructure and other kinds of matters, and whether there's clean water or not are moot to this discussion. This bill has a potential to save lives. You asked, “How will we go forward?” You mentioned that you voted against this in the House of Commons. I don't know if that was a vote of conscience. If it was, I encourage you to vote it again at third reading, but, please, do not put up a procedural block to the transfer of sponsorship that will not allow proper debate and proper use of your vote, one way or the other, at third reading.

**The Chair:** Thank you, Madam Watson. I appreciate the passionate response you have on this, but we have only about three minutes left now.

Monsieur Bouchard, any time we go over we're taking from the next panel, so be as brief as you possibly can, please, sir.

[*Translation*]

**Mr. Robert Bouchard:** Thank you, Mr. Chair.

Good morning, ladies and gentlemen. My first question is for Mr. Perry.

Mr. Perry, you said that CAMR can work. Earlier, a member said that, over a period of five or six years, the regime was used only once. Why is CAMR underused? It's clearly underused. Why is that?

[*English*]

**Mr. Grant Perry:** Again, I can only speak to that to the extent that what has been effective, has been effective when it has been used. It took a very short time, as we've talked about. I can't speak to why other countries have not used it. You can postulate around it: is it an issue of voluntary licences, partnerships that are being developed elsewhere? Is it a question that the price is coming out of Indian, Brazilian, and South African generics that are substantially lower than Canada's, or is it our ease of access? There are a number of factors that contribute to it, but with a lack of attempt to use it, it indicates to me there's a lack of need for that particular piece of legislation. It does not mean there's a lack of need to meet humanitarian goals in the developing world, but if they're not accessing the legislation, I can't speak to why not.

[*Translation*]

**Mr. Russell Williams:** Mr. Bouchard, I can get you copies of documents issued by the Access to Medicine Foundation, which conducted an assessment of global trends. To answer your question, we began using our generic medicines through more voluntary and more creative measures. We could provide you with a long list of voluntary collaboration examples.

I think that we are beginning to see that in the case of our generic products and of patients who need them, there are quicker, more flexible and more effective measures than those included in the legislation. I think that we all want to do the same thing, but we must ask ourselves how we can save lives. Everyone is seeking ways to function as effectively as possible on a global scale. I would like to reiterate that, often, by collaborating with the makers of innovative and generic products, we find solutions that are independent from this legislation.

● (1130)

**Mr. Robert Bouchard:** You're talking about voluntary measures. You also said, Mr. Williams, that there's room for improvement. Aside from the amendments set out in Bill C-393, what changes could remedy CAMR's shortcomings?

**Mr. Russell Williams:** I think that all committee members could simply get in touch with generic medicine companies, encourage them to use the regime and discuss voluntary measures with them. That way, we could move forward together and find much more creative solutions. I don't think that amending the legislation is necessary.

**Mr. Robert Bouchard:** Thank you.

[*English*]

**The Chair:** Thank you, Monsieur Bouchard.

Thank you to all of our witnesses, both those present as well as by video conference.

We'll now suspend for five minutes.

Please, I would ask the other witnesses to make their way to the table. If you have conversations with the present witnesses, members, please take it outside so that we can make the transition in the room.

● _____ (Pause) _____ ●

● (1135)

**The Chair:** Ladies and gentlemen, we're continuing our 40th meeting now. I'd just like to let the witnesses know, both by video conference as well as live here, that I'm going to introduce you in a second.

For the witnesses and guests in the room, the members have been here since 8:30 this morning, and I think many of them had meetings prior to that as well. So if you see members getting up to go back to grab a morsel of food, please don't take offence to that. It's because I wouldn't want them to falter and pass out here from lack of nourishment.

In front of us we have Jim Keon, who's president of the Canadian Generic Pharmaceutical Association, and Jody Cox, director of federal government relations. As well, we have David Schwartz, chair of the biotechnology patents committee with the Intellectual Property Institute of Canada.

By video conference...now I only see one person actually in front of me, but I see four squares by video conference, so I'll just make the introductions and hopefully they will come on the screen momentarily. There's Paula Akugizibwe, from AIDS and Rights Alliance for Southern Africa. As well, we have Andrew Jenner, director of intellectual property and trade with the International Federation of Pharmaceutical Manufacturers and Associations. We have Frank Plummer, scientific director general, national microbiology laboratory, for the Public Health Agency of Canada; and Antony Taubman, director of the intellectual property division with the World Trade Organization.

The witness we have in front of us now is Mr. Plummer.

Mr. Plummer, good morning.

**Dr. Frank Plummer (Scientific Director General, National Microbiology Laboratory, Public Health Agency of Canada):** Good morning.

**The Chair:** Mr. Plummer, can you just say a few words, so we can make sure we have a good audio for you?

**Dr. Frank Plummer:** Sure. Hello, everybody. It's good to be here early in the morning in Seattle.

● (1140)

**The Chair:** Thank you very much.

Mr. Plummer, because you're the one person we have by video conference and the technology is working, we're going to let you go ahead with your opening comments for five minutes, please.

**Dr. Frank Plummer:** Good morning again.

My name is Frank Plummer. I'm the scientific director of the National Microbiology Laboratory in Winnipeg and the chief scientific officer with the Public Health Agency of Canada. I'm also a distinguished professor at the University of Manitoba and a physician scientist who has spent his career working on HIV and AIDS in Africa. It is in those latter capacities that I'm appearing before the committee today.

I would like to thank the committee for soliciting my input and giving me the opportunity to talk about some of my work and, moreover, allowing me to appear from Seattle. I'm attending an important meeting of the Gates grand challenges in global health program, which I couldn't afford to miss.

I'd also be remiss if I didn't thank the Gates Foundation for the gracious loan of their video conferencing facilities.

I know the committee is reviewing legislation to make Canadian-made generic drugs still under patent by non-generic pharmaceutical companies more accessible and affordable for developing countries, and that the original legislation was targeted largely to antiretroviral therapy for HIV.

First I'd like to tell the committee about some of the amazing work Canada has done related to the HIV epidemic in Africa. I lived in Nairobi for 17 years, directing a highly acclaimed collaboration between the universities of Nairobi and Manitoba. The research done through this collaboration was among the first to recognize that HIV was widespread in East Africa and did pioneering work to understand the epidemic and how to prevent the transmission of HIV.

As committee members will know, HIV is transmitted primarily through heterosexual relationships in Africa, and it also spreads from mother to newborn child. Through research funded largely by the Government of Canada, we learned that commercial sex is a key driver of the HIV epidemic. Ordinary sexually transmitted diseases such as gonorrhea and chlamydia promote HIV transmission. Circumcision of men reduces their susceptibility to HIV, and breast feeding is an important risk factor for transmission of HIV from mother to child.

Each of these understandings was translated into effective interventions by our group and ultimately changed global health policy. They make up the core of effective HIV prevention in Africa and elsewhere. Many tens of thousands of people don't get HIV infected each year because of this foundation work done by the universities of Manitoba and Nairobi and funded by the Government of Canada.

This long-standing collaboration and my involvement in it continue. This year we celebrated our 30th anniversary. In recent years the research work of the collaboration has focused on understanding natural immunity to HIV. This work, which may discover how to make an HIV vaccine, is funded by the Government of Canada and the Bill and Melinda Gates Foundation, which is why I'm here in Seattle today.

The work is carried out in a state-of-the-art laboratory complex built and equipped with a grant from the Government of Canada through the Canada Foundation for Innovation. So Canada has done and continues to do a lot in the fight against HIV and AIDS in Africa.

Now to Bill C-393. It is beyond my competence to comment on whether the current legislation and proposed amendments to it are problematic or not. I know there's been criticism of the effectiveness of the current program and only one country has yet accessed it. However, I doubt that the structure of the Canadian program has anything to do with why it's not being used. I think most likely the original, well-intentioned program was overtaken by events. The global fund to fight HIV, tuberculosis, and malaria, the U.S. PEPFAR program, the President's emergency plan for AIDS relief, the availability of high-quality antiretrovirals from generic manufacturers elsewhere, and drops in the price of non-generic drugs all contribute to a lack of interest in the Canadian program, and that's seen with other programs of a similar nature around the world.

Unfortunately, you were unable to hear from my colleague, Dr. Kimani from Nairobi, but it's his experience that availability of antiretroviral drugs is not the real problem. The ability to deliver high-quality treatment programs with qualified personnel is more of a problem.

While I'm certainly supportive of making antiretroviral drugs available to those who need them, I would also remind the committee that the current antiretroviral drugs are not cures. Importantly, they prolong life; however, it's my belief we will not solve the HIV pandemic by treating AIDS. People are becoming newly infected with HIV at a far greater rate than they are being put on treatment. Furthermore, treating AIDS is many times more expensive than preventing an HIV infection. We know how to prevent new infections effectively and inexpensively, and in my view, far too little emphasis and investment has been put into simple preventive strategies that we know work. We also need to focus research on technologies to prevent HIV transmission such as a vaccine or a microbicide.

● (1145)

I'll close there with a thank you for asking me to speak to you today, and for your attention. I look forward to your questions.

**The Chair:** Thank you very much, Dr. Plummer.

We will now move on to Mr. Keon, for five minutes, please.

[*Translation*]

**Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association):** Thank you, Mr. Chair.

[*English*]

Thank you, ladies and gentlemen.

We're pleased to have the opportunity to speak to Bill C-393.

I represent the generic pharmaceutical industry, which has been an important part of the Canadian economy and health care system for more than 50 years. We are fortunate to have a large and sophisticated generic drug industry in Canada. Today it directly employs approximately 12,000 Canadians in high-skilled manufacturing and R and D positions.

Most of the generic drugs sold in Canada are manufactured in world-class facilities right here in Canada. The largest drug company in Canada, brand or generic, is Ontario drug maker, Apotex. The largest drug company in Quebec, brand or generic, is Pharmascience, also a generic.

Our industry fills six out of ten prescriptions in Canada today, and that number is growing quickly. There has been talk recently about the price of generic medicines in Canada and the ability to supply good-quality medicines at good prices abroad. Generic prices in Canada have traditionally supported pharmacy strongly. That system is changing. Provincial governments are changing that system. Generic drug prices in Canada have come down dramatically over the past year, as pharmacy funding is now being looked at in a different manner. Generic drugs have provided value for the Canadian health care system and are providing better value than ever.

In addition, Canadian generic drug makers actively support international humanitarian aid efforts. CGPA member companies are among the leading donors to Health Partners International of Canada, a non-profit relief and development organization that works through other partnerships to increase access to medicine and improve health in the developing world.

Our members are also active more recently in relief efforts in Haiti, donating millions of dollars worth of medicine through organizations like World Vision, Feed The Children, and Health Partners International.

This committee is studying a particular mechanism aimed at delivering drugs for humanitarian purposes to the developing world, Canada's access to medicines regime. The World Trade Organization decision, which is a decision of 120 countries, that led to the creation of CAMR, is a result of international recognition that the needs of the developing countries were not being met solely by the brand-name industry. Brand companies were generally unwilling, without competition, to lower their prices for drugs under patents to levels that these developing and least-developed countries could afford. That's why the international community came together and developed the so-called Doha agreement.

CAMR provides a legal and regulatory mechanism under which generic manufacturers in Canada are permitted to develop, produce, and export medicines covered by domestic patents to developing and least-developed countries for humanitarian purposes.

We've heard about some of the complexities of the regime, and we know that despite those, Apotex has developed and produced two shipments of its triple combination AIDS drug, Apo-TriAvir, to Rwanda. Unfortunately, the company has publicly stated that it will be difficult to use the regime again without changes being made.

There has been a lot of discussion this morning about whether CAMR works in its current form. The Canadian Generic Pharmaceutical Association's answer is no. Apotex's answer is no.

The problem with CAMR, which makes it ultimately unworkable, is the licensing scheme. The WTO decision that led to the creation of CAMR outlines four basic requirements that need to be met for an exporting country to grant a compulsory licence to a generic manufacturer, and these could have more easily been implemented by Canada. Instead, the CAMR licensing process is backwards; it is largely a process controlled by the interests of intellectual property rights holders and not the interests of those who desperately need access to life-saving medicines in times of health crises.

As outlined in our brief, CGPA supports the changes to the Patent Act that are outlined in Bill C-393. In our view, the streamlined application and licensing process in the bill embodies the spirit of the Doha declaration and the WTO decision, while at the same time ensuring Canada's compliance with its TRIPS obligations.

We have one issue with the bill, and that relates to the proposed amendment to the Food and Drugs Act that would allow for foreign drug approvals under CAMR. In our view, this is not necessary, and it's not supported by our association. The generic pharmaceutical industry continues to support a Health Canada approval.

● (1150)

With that, I will conclude my remarks, as I'm sure you will have several questions for the panel. I would be pleased, along with my colleague, to answer any questions you may have regarding Canada's access to medicines regime.

Thank you.

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

We still don't have any of the other participants by video conference, so we'll go to Mr. Schwartz for five minutes.

**Mr. David Schwartz (Chair, Biotechnology Patents Committee, Intellectual Property Institute of Canada):** Thank you, sir. *Bonjour*, and good morning.

My name is David Schwartz. I'm a lawyer and a patent agent. I'm a partner in the firm Smart & Biggar, and I appear here today on behalf of my professional association, the Intellectual Property Institute of Canada, or IPIC.

[*Translation*]

I'm pleased to appear before you today on behalf of IPIC.

[*English*]

IPIC is the professional association in Canada of patent agents, trademark agents, and lawyers practising in all areas of intellectual property law. I'm the chair of IPIC's biotechnology patents committee and appear here today in that capacity. I have practised exclusively in the patent field for 17 years. My technical background is in genetics and my work principally involves assisting inventors in obtaining patent protection for their innovations at the Canadian patent office and those of other countries.

I hope I can provide some contributions to the very thoughtful and informed discussion we've heard this morning.

It's accepted that innovation is important to the economic and social well-being of our country. Patent legislation is a key element of any country's innovation system, and this legislation must achieve a fine balance between competing policy goals and must conform with a number of international treaties.

IPIC's expertise is in intellectual property law and not the manufacturing of medicines or the policy concerning assistance to developing countries. Our submission, therefore, is limited to studying the compliance of Bill C-393, in the form that we've seen it so far, I would emphasize, with the TRIPS agreement, and its possible effect on the patent system in Canada and elsewhere.

The TRIPS agreement of the WTO sets out agreed minimum standards for the protection of intellectual property rights. Member states may therefore provide more extensive protection than required by TRIPS, but they're not permitted to establish laws that provide less protection than required under the TRIPS agreement.

To use a very simplistic analogy, consider speed limits in school zones. If a provincial law, a law of Ontario, requires that the speed limit in a school zone be no more than 40 kilometres an hour for safety, the City of Ottawa would be permitted to lower the speed limit to 30 or 35 kilometres an hour, but we couldn't raise it to 50. I am going to come back to that point toward the end of my comments.

Article 31 of TRIPS provides for use of a patent invention by someone other than the patentee without the authorization of the patentee, in certain circumstances. Now importantly, paragraph (f) provides that the use of the invention shall be authorized predominantly “for the supply of the domestic market”. That would mean Canada. There are also requirements about remuneration of the patentee in the domestic market. These requirements are problematic for those countries that don't have the manufacturing capacity or technical expertise in their own markets, that is, in their own countries, to make and use a patented invention, even if they had the authorization to do so.

So the general council decision of the WTO in 2003 implementing paragraph 6 of the Doha declaration provides a solution to this problem—and I know we've already heard about it this morning. It waives paragraphs (f) and (h) of article 31 for pharmaceutical products in certain circumstances and sets out the requirements of a country, typically a least-developed or developing country, to import patented medicines under the waiver. The general council decision is, of course, implemented in Canada in the Patent Act as CAMR.

I emphasize these two points because the Canadian legislation must therefore comply with two significant aspects of TRIPS. First, there must be requirements for the rest of article 31 that wasn't waived. Second, the waiver of paragraphs (f) and (h), if it's to be used, must be done in accordance with the requirements of the general council decision, which is that it be used in good faith to protect public health, and not as an instrument to pursue industrial or commercial policy objectives. This purpose would be defeated if products supplied under the decision were diverted from the markets for which they were intended. Accordingly, all reasonable measures are to be taken to prevent such diversion in accordance with the relevant paragraphs of the general council decision. These over-arching principles are explained in the chairperson's statement that was associated with the general council's decision, which I'm effectively quoting from.

If the Canadian legislation is not in compliance with TRIPS, the legislation is at risk of being challenged under the WTO dispute settlement procedure. Twice already, both times in 2001, it has been necessary to amend Canada's Patent Act as a result of challenges by other countries, where the WTO found that our law was not in compliance with TRIPS. In one instance, the challenge involved a complaint by the European Union about our stockpiling provisions, which Mr. Dearden mentioned. There was another instance, also in 2001, where we amended the act to change the term of patent protection after a complaint by the United States. So twice already we've amended our act in recent years because of complaints.

Objections in an international forum that our Patent Act doesn't comply with TRIPS create uncertainty and may diminish Canada's reputation as a country that respects IP rights, negatively affecting domestic and foreign investment in research and development. Thus, in our view, it is important that CAMR be compliant with TRIPS, so that it does not invite objections as described above.

● (1155)

This involves not only ensuring that the black-letter provisions of article 31 and the general council decisions are met, but also ensuring that the procedural aspects of the legislation provide the appropriate, practical safeguards to ensure that the purpose and intent of the waiver set forth in the general council decision is met.

To return very briefly to my speed limit analogy, sure, we can set a speed limit of 35, but if we don't inform the public of the speed limit, if we don't post signs, and if we don't have police to monitor the speed, then the limit is really, for practical purposes, not effective. So we have similar concerns with respect to some aspects of C-393.

To conclude,C-393 has clearly created debate. We've learned that this week and last week, and it has raised awareness about very important issues. However, as you'll see from our very detailed written submissions, we have concerns with respect to the bill's compliance with TRIPS and the general council decision, and we've identified some patent-specific issues as well.

[*Translation*]

Thank you for inviting us to appear.

[*English*]

Thank you for inviting our association to appear here, and I'd be very pleased to address any questions you have today.

Thank you.

**The Chair:** Thank you very much, Mr. Schwartz.

It appears that we've run out of witnesses, and we're having a challenge today—at least by video conference anyway. So we're going to go to our rounds of questioning now.

Over to Mr. Garneau for five minutes.

**Mr. Marc Garneau:** Thank you, Mr. Chair.

My first question would be for Mr. Keon.

You say that the generic industry in Canada has had experience working with Health Partners International and other organizations, such as Feed the Children.

We're told that 95% of the drugs that are on the WTO list are not protected by patents, and I'd be interested, from the generic industry's point of view, to know how much involvement you have for these large numbers of drugs that are not patent-protected.

What kind of involvement does the Canadian generic drug industry have in Africa with non-patented drugs?

**Mr. Jim Keon:** As I mentioned, the generic companies are major contributors to Health Partners International. That's the group in Canada that deals most consistently with donations of medicines abroad, so we work very actively with them. Generics are now again filling the majority of the medicines they ship.

The generic industry in Canada is in many ways an international industry. So we have companies like Teva, Sandoz, which are large international companies that also have operations in Africa. Traditionally they can also supply drugs from elsewhere to Africa.

We do have Canadian-owned companies like Apotex and Pharmascience that ship directly from Canada and are active. Our industry is shipping products to over 140 countries around the world, including Africa.

**Mr. Marc Garneau:** You don't happen to have a dollar figure, do you, for this?

**Mr. Jim Keon:** I do not.

**Mr. Marc Garneau:** Okay. All right.

Mr. Schwartz, there are different interpretations as to whether C-393 would result in a violation of our TRIPS agreements, and we've heard different people say it does and others say it doesn't. I believe you fall into the camp that says that we could be challenged on it. You spoke about article 31, and you spoke about the waivers associated with pharmaceuticals in certain cases.

I'd like to get a little bit more of a feeling. Let's say we have a situation where Canada is challenged. Let's say C-393 is accepted and we are challenged. What are the practical implications for a country like Canada? Intellectual property is pretty dry stuff. But for Canadians, I think it's important for us to understand the implications if somebody successfully challenges Canada on a violation of the TRIPS agreement.

● (1200)

**Mr. David Schwartz:** Thank you.

First, in terms of your preliminary remarks about where we fall, that's obviously a difficult issue. If you have read our submission, you will see that it really doesn't take a strong position one way or another, but it identifies the areas of possible concern. In fairness, you've heard people with much more expertise about TRIPS than I will ever have come at it from two different perspectives. That's the nature of these proceedings, and I would expect eventually the government has resources—Justice, the patent office lawyers—who can study these competing views and assess them.

To answer your question about what would happen, of course, we don't know the long-term outcomes. My concern would largely be... in some respects, it's a question of perception. We've agreed to minimum standards within TRIPS. We've agreed to minimum standards in NAFTA. Do we want to go forward with a bill or a law that could invite criticism and possibly have another challenge, whether or not successful? Of course, we heard today that no one would challenge this, or a challenge would succeed or fail. Our position is largely that, ideally, the appropriate balance would be struck first so that this doesn't happen.

From my perspective, I don't think it's a particularly good thing for our reputation, as protecting innovation, to twice have the provisions of our Patent Act struck down as being offside TRIPS. It's a position being taken in the international community, and I suppose it's common sense. We've agreed to have an act that is compliant with TRIPS, and how does it look, twice already, to have been demonstrably wrong and put forward legislation that doesn't comply with our agreements? That's almost a matter of fact, I think.

**Mr. Marc Garneau:** Thank you.

One last quick question for Mr. Keon. CAMR, as it exists at the moment—and I'll say it again, I wish Apotex were here because they were centrally involved. Essentially what you're saying, representing your industry, is that CAMR doesn't work. I'd like you to tie it to the specific example where it was used once. What were the big obstacles?

**Mr. Jim Keon:** I think Apotex is a leader in Canada. It took the opportunity, the challenge, and went forward. I would say that there was tremendous enthusiasm within that company. People worked long hours, they worked weekends and evenings to try to get the product approved as quickly as possible. There was a great sense that they were doing something important when they did it.

When I talked to the Apotex executives...I think they found that the whole process was very lengthy, uncertain, and led to too-small shipments. The process would have to be started again. Apotex and other companies are able to provide good prices and volume products by being large-volume producers. They don't specialize in little shipments, buying a product or making a small amount and selling it. That's not the way to get good prices. That's not the way to develop economies of scale. If they've identified a product and work as they did in the past with Doctors Without Borders and with Health Canada, and see a need for a product that they've developed, they'd like to be able to produce that in large quantities, subject to the rules, but then sell it with some certainty. They don't have that, and that's really, I think, in large measure why they found this process unsatisfactory.

**The Chair:** Thank you, Mr. Keon, and thank you, Mr. Garneau.

It looks like we may actually be aggregating some of our witnesses now. Please be patient with me for a moment, members.

Is there anybody in the room in Cape Town right now who can hear my voice and possibly come to the microphone?

Mr. Taubman, can you hear me?

● (1205)

**Mr. Antony Taubman (Director, Intellectual Property Division, World Trade Organization (WTO)):** Yes, I can. Good afternoon.

**The Chair:** That's great.

Mr. Taubman, go ahead with your opening remarks, for five minutes.

**Mr. Antony Taubman:** Thank you very much, Mr. Chair.

Honourable members, I thank you for the invitation to appear before this committee on your deliberations on a matter of fundamental importance to the international community, that of ensuring access to vital medicines by those in most pressing need of them.

I have to say that it's unusual for someone in the WTO Secretariat to contribute to a national legislative and policy-making process in this immediate way, but I understand that some technical input from the WTO Secretariat may assist you in your deliberations, just as it was sought by the Senate Standing Committee on Banking, Trade and Commerce concerning the analogous Bill S-232, which led to an appearance before that committee in November last year.

I made an extended statement on that occasion, which is now on the record. So as not to outstay my welcome today, I would like to refer to that statement and ask, if possible, that the committee take note of the detailed clarifications and explanations concerning my status that we recorded on that occasion. However, I should reiterate that I do not appear before you as an independent expert with latitude to offer personal opinions nor as an advocate of any policy position or approach to legal interpretation. Equally, I'm not here to represent the World Trade Organization, as such. Rather, I work within the secretariat of the WTO, and I can offer input to your committee only at a technical level.

My position is something like that of the staffers, in fact, who organize and support your committee hearings, rather than that of an independent voice. I currently serve as director of the Intellectual Property Division of the WTO, where I work with a small but talented and dedicated group of colleagues responsible for the administration of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, the TRIPS agreement. We service the TRIPS Council, a body within the WTO that comprises all of our members, that is to say, the 153 members of the WTO.

The TRIPS Council is in fact meeting right now and is just about to undertake its annual review of the paragraph 6 system you are considering in your deliberations. We also manage notifications and formal procedures under the TRIPS agreement, and we provide technical assistance and training, especially for developing countries. Again, this is an important part of our work in relation to the paragraph 6 system and public health. We do this in cooperation with our international partners, including the World Health Organization.

There are certain roles that we cannot offer you as a secretariat. Unfortunately, these may coincide with the very kinds of inputs that could be most useful to your committee. In particular, I can't offer any views on the interpretation of our legal texts—the TRIPS agreement and the amendment—and still less on the compatibility with TRIPS of any existing or proposed Canadian legislation. This position, I know, may appear to be evasive or unhelpful. I emphasize that it's emphatically not. Rather, it stems from sound policy reasons and a consensus among our members as to our appropriate role as a secretariat.

We are, however, responsible for supporting our members with respect to the appropriate way forward on the implementation of TRIPS and the paragraph 6 mechanism, and we have a responsibility to provide as much technical assistance as we can. However, our members collectively don't consider it helpful if a technical secretariat seeks to pass judgment on domestic legislative proposals or to make assessments as to whether the legislative choices comply with the TRIPS obligations in a legal sense. That's really a matter for our members to take up amongst themselves, and that's something I can elaborate on if it's useful to the committee.

There is a process of analysis and review of national legislation. Intellectual property legislation, including Canada's access to medicines regime, is normally notified to the TRIPS Council, to this formal body. The council then reviews the legislation. There is a peer review process whereby other members, other nations, raise questions about the legislation and seek clarification on it. But even the TRIPS Council itself is not empowered to then make a determination as to whether the legislation is compliant with TRIPS, even though our members have indeed, as a matter of policy, generally expressed a firm policy resolve to ensure that the legislation complies with TRIPS.

● (1210)

There are other processes, such as the trade policy review, that also look at aspects of the national trade regime. Indeed, Canada's most recent trade policy review in 2007 looked at the access to medicines regime, among many other aspects of Canada's laws and regulations.

However, none of these processes lead to any formal assessment of compliance with international obligations. If there are concerns about non-compliance, it's really up to another WTO member. If they happen to be sufficiently concerned to take up the matter formally, it's up to that member to follow one of several courses of action. One of these is to lodge a formal complaint, which can lead to formal disputes and proceedings. This can ultimately lead to an independent panel that will consider whether the law is consistent or not with obligations.

But the secretary itself certainly doesn't initiate any such compliant process. It really would be at odds with our essential role, and we don't offer any assistance on compliance on request or even by our initiative.

**The Chair:** Mr. Taubman, is that just about the conclusion?

**Mr. Antony Taubman:** Yes. I wanted to mention some of the technical cooperation relating to paragraph 6, but I'm happy to pass that up if you prefer to move on.

**The Chair:** That would be good. Thank you very much.

I think Cape Town has joined us and Madam Akugizibwe.

**Ms. Paula Akugizibwe (Advocacy Coordinator, AIDS and Rights Alliance for Southern Africa):** My apologies for the wait, sir.

**The Chair:** I'm glad you could join us.

I'll go to Mr. Jenner now, who has been on for a while, with his opening comments. Then we'll go back to Cape Town.

Mr. Jenner, please begin. You have five minutes.

**Mr. Andrew Jenner (Director, Intellectual Property and Trade, International Federation of Pharmaceutical Manufacturers and Associations):** Thank you very much.

I hope you can hear me okay.

**The Chair:** It's very good. Thank you.

**Mr. Andrew Jenner:** Thank you very much for allowing me to give evidence at this hearing. I represent the International Federation of Pharmaceutical Manufacturers and Associations, which is based in Geneva. We're a global not-for-profit NGO that represents the research-based industry. I am from the biotech and vaccine sectors. It has over 25 leading pharmaceutical companies and 46 national and regional associations from around the world.

I'll start my comments by really focusing on what we are trying to achieve with the access to medicines agenda, that is, certainly a sustainable access to quality and effective medicines. I think it's something you have heard, no doubt, before, but we really do need to have a useful picture of where this compulsory licensing provision, if you like, fits into the wider framework.

In order for us to achieve our shared goal, there are certain key components that need to be in place in order for us to get access to medicines. We know well about the importance of health care systems in countries. When I was working in government, I frequently worked on this area during the EU negotiations, and it was agreed to in the U.K.

A senior health official from Botswana made quite a stark comment by saying that you could drop all the medicines in the world in Botswana and it would make no difference to the situation there, because he realized the lack of infrastructure—and I know there are numerous comments that we could draw to there. As an example, the director of the WHO HIV division publicly said in 2006, and I quote:

> Africa has been hardest hit by the AIDs epidemic…it is very obvious that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems. You have health infrastructure that is dilapidated, and supply chains that don't exist.

When we talk about access to medicines, we really do need to make sure we have effective health care systems and infrastructure in place, and health care officials are able to administer those medicines effectively and appropriately.

When we look at the actual medicines, this of course is a key part of the access puzzle. Some 95% of the medicines on the WHO essential medicines list are not covered by patents. That's not to say that the other 5% is not very important, but that really does put, if you like, this debate into context. We're talking about a small number of medicines. That could increase over time, of course.

What I'd like to do now is focus on the successes there have been over the last number of years that have not relied upon compulsory licensing provisions at all. The number of patients treated for HIV/AIDS went from 500,000 patients in 2003 to 1.57 million patients in January 2005. For example, the 3,140% increase between 2004 and 2006 was not achieved by any use of the compulsory licensing provisions.

Just to draw my thoughts to a conclusion, as the WTO director general has said, "Measure of success should not be the number of compulsory licences issued. But in our view it should be exactly what is happening on the ground in the access to medicines area."

There's been a massive expansion of new initiatives for global funds, like the Bill and Melinda Gates Foundation, just to name one example. This increase in access to medicines does not rely upon compulsory licensing provisions. So we need to manage expectations that any amendment of a Canadian bill will not result in increased access to medicines.

But certainly, from a Geneva perspective, Canada manufactures high-quality generics, of course, but they are expensive. It is thought that for many of the countries in the Geneva context, the prime routes to get these patented medicines, which are necessary in generic form, you'd go to India or even China or other markets.

Certainly, when I was negotiating the EU regulation that implemented the same provisions across the EU, it was a well-known public fact that we thought at that time that the use of this provision would not be extensive, given the commercial considerations and the cost of medicines in Europe.

● (1215)

Thank you very much.

**The Chair:** Thank you very much, Mr. Jenner.

We are now on to Ms. Paula Akugizibwe. I hope I got your name at least close. Thank you very much for investing your time. Please go ahead with your remarks, for five minutes.

**Ms. Paula Akugizibwe:** Thank you for giving me the opportunity to address the committee on this.

I work with the AIDS Rights Alliance for Southern Africa, which is a regional African organization of NGOs that are connecting people living with or affected by HIV. I'm not in a position to give you a detailed legal analysis of the proposed amendments, but I'm going to restrict my comments to three main points.

First is the affordability of medicine, one of the most critical influences of the political world...[*Inaudible—Editor*].

Secondly, the global HIV...[*Inaudible—Editor*]...in which decisions like this, which have major impacts, and this is the role of Canada in ensuring that developing countries have access to generic medicines from generic producers...[*Inaudible—Editor*]...is more important now than it has ever been in the past.

● (1220)

**The Chair:** Ms. Akugizibwe, is there a way that you can move the microphone closer to you? Is it possible for you to have the microphone closer to you as you speak?

**Ms. Paula Akugizibwe:** I'm going to ask for some assistance. Can you hear me? Can I carry on in the meantime?

**The Chair:** You can carry on, but it's pretty difficult to hear you.

**Ms. Paula Akugizibwe:** Is that better?

**The Chair:** Much better.

**Ms. Paula Akugizibwe:** Okay.

I'm sure everyone is familiar with the fact that in 2007 Rwanda took a landmark step of notifying the WTO of its potential interest in importing a fixed dose combination of AZT, 3TC, and nevirapine from Apotex.

Beyond the global significance of being the first and in fact only country to benefit from this compulsory licensing possibility, the step carried a lot of significance in the national context, in that it was a necessary and unprecedented demonstration of the country's political commitment to the fight against HIV. It came at a time when Rwanda was transitioning to optimal treatment guidelines in keeping with the latest developments in international best practice; that is, moving away from D40-based regimens for HIV treatment to AZT-based regimens and shifting the threshold for initiation on ARV treatment from 200 to 315.

Rwanda was one of the first countries on the continent to adopt these guidelines and was therefore immediately faced with the significant cost implications that they entailed. At the time, best untried, best-priced ceilings—the shift from D40 to AZT—would entail a more than 30% increase in the cost of the drugs alone.

In 2007, although there were three Indian pharmaceutical companies manufacturing a combination of this nature that had been prequalified by the WHO, only one of these suppliers had agreed to charge low-price ceilings. So Apotex presented as the only competitive supplier for the tender.

Following the process, which was widely regarded as extremely cumbersome and quite prohibitive for future possibilities, the licence was ultimately granted, which allowed Apotex to successfully bid for the ARV tender at a competitive price, and that put Rwanda's efforts to accelerate treatment to the point at which it is now one of only two countries on the continent that have achieved better access to HIV treatment based on WHO guidelines.

I know that everyone is probably extensively familiar with this story, but I'm telling it to you again to emphasize the central point of my message today, which is that access to affordable ARVs often presents the critical catalyst or the critical inhibitor in realizing political ambitions to scale up universal access to HIV services.

James Orbinski, a Canadian academic, wrote in the *Public Library of Science* last year that for many in developing countries who live on less than $2 U.S. a day, access to health care technology is little more than a dream. Further, if a treatment is too expensive, other factors that can affect a medicine's availability, such as drug distribution systems and national drug use policies, become moot. It was only when generic competition lowered the price of antiretroviral therapy for HIV that the policy debate shifted from whether such therapy was possible in resource-poor settings to how to strengthen health infrastructure to provide comprehensive health care for people in such settings.

And I think this ties into the point that was made by the previous speaker about how a health care official in Botswana said that he could deliver all the best medicines in the world, but that without the infrastructure those medicines would mean nothing. I think that point is quite intuitive, just as the contrary to that point is intuitive, namely that you could have the best infrastructure, but without affordable medicines the infrastructure would not mean much.

I think the caution here is that we shouldn't get drawn into a whole dichotomy. Of course we need good health systems, but at the same time, without affordable medicines the country's ability to commit to scaling up systems to provide services—if it doesn't have the drugs that define the line between life and death—often greatly inhibits their political commitment to doing so.

When affordability is not certain, countries are forced to make compromises that can significantly affect the success of their programs. Recently, the chair of the South African national AIDS commission, introducing the country's new guidelines, stated that a tricky balance had to be struck between the top-range drug regimens, which are costly, versus some regimens that are cheaper but have more side effects. I think the point to realize here is that we're not only looking at how drug affordability affects a country's ability to scale up treatment, but also at decisions on what quality of treatment is scaled up from these countries.

For example, D40, which in many developed countries is not being used in treatment protocols anymore, is still being used in many sub-Saharan African countries simply because the cost of switching to AZT is prohibitive for many health systems. The spinoff of this is that many patients.... Recently a study in South Africa showed that within three years 21% of patients on D40 stopped taking the treatment because the toxicities are unbearable. But the more tolerable drugs, such as AZT, are less affordable, and therefore we are insisting on maintaining drugs that are not optimal.

● (1225)

It is similar to increasing treatment thresholds for initiation: whether someone is initiated at a CD4 of 200 or a CD4 of 315 is to a large degree affected by affordability of medicines.

Currently the global funding situation for HIV is looking quite dire. The recent replenishment of the global fund has left deep-seated anxiety in many people, because the amount that was pledged is barely going to be enough to sustain treatment programs, let alone to scale up.

Even before the global funding crisis for HIV that we witnessed over the past year, countries have begun to call the sustainability of treatment programs into question because of the cost of the medicines.

In Botswana, which for many years has been the poster child of the ARV rollout on the African continent, two years ago the president publicly stated that continued enrolment of new patients in treatment must be guaranteed beyond 2016, because it's possible treatment can be sustainable.

In this time of financial austerity, it's really crucial that we take every measure possible to reduce the cost associated with HIV programs, and one of the most critical opportunities to navigate this cost is in the area of drug procurement. Many countries are now looking to reduce the nine-drug cost associated with provision of ART. But while health systems can be changed through task-shifting and through decentralization to adapt to the changing economic context, the simple, concrete need for the drugs to keep people in these systems will not change, and it's just as critical as it was five years ago when this legislation was introduced. The only difference now, I guess, is that the role of Canada in the global generics field is even more crucial than it was in 2004.

Frankly, we're generating added competition that will even further drive down the prices of medication, something that is desperately needed given the funding crisis that I mentioned as well as the potential threat to accessing generics from Indian companies, which could possibly result from the free trade agreements that are currently being discussed between India and the EU.

**The Chair:** Madam, I'm going to have to cut you off there. We're way over time. If you need to make some other points, try to do so during the question period. We'll continue with questions from other members now.

[*Translation*]

Mr. Malo, you have five minutes.

**Mr. Luc Malo:** Thank you very much, Mr. Chair.

I want to thank all our witnesses for joining us today.

My first question is for Ms. Akugizibwe, and perhaps also for Dr. Plummer, who mentioned his work in Nairobi during his presentation. He could perhaps answer me.

During our discussion with the previous panel of witnesses, we tried, with the help of a Doctors Without Borders representative, to understand why Apotex took so long to deliver the medicines. The reason given was that it was difficult to come to an agreement with a recipient country. The representative said that potential recipients were not quite sure how to use Canada's Access to Medicines Regime.

Is that your experience as well? Is that what you see in the field?

● (1230)

[*English*]

**Dr. Frank Plummer:** Is that directed to me?

[*Translation*]

**Mr. Luc Malo:** Yes, if you want to answer it.

[*English*]

**Dr. Frank Plummer:** I don't have any experience with CAMR directly. Certainly the regulatory strength and procurement skills in many developing countries are quite challenged. I expect that could be a problem, but I don't have any personal experience with this issue.

**The Chair:** Somebody could answer that.

[*Translation*]

**Mr. Luc Malo:** Could Ms. Akugizibwe, who is in South Africa, perhaps answer my question?

[*English*]

**Ms. Paula Akugizibwe:** Yes, I can venture a response. From my understanding of the process, one of the reasons it took a long time was that the legislation requires that the country first express its desire to purchase the drugs from the Canadian company, which is a bit of a catch-22 situation, because in order for that to happen, the company has to be able to take part in the national tender process, which would require the compulsory licence.

I think one of the greatest advantages of the amendment to this legislation is that there would be a sort of one-licence submission, whereby the company would not require a country to come forward and explicitly express interest in order to be able to export these drugs. That would greatly reduce the bureaucratic impediments in future.

[*Translation*]

**Mr. Luc Malo:** Do you think that prospective recipient countries know how to use the current regime?

[*English*]

**Ms. Paula Akugizibwe:** I'm afraid I can't actually comment on that; I haven't had enough direct conversation with people who have attempted to use the regime.

But from what I was familiar with when I was in Rwanda, which is around the time these negotiations were taking place, I think there was certainly a great deal of confusion around the bureaucracy that was created through the procedures entailed in this legislation.

[*Translation*]

**Mr. Luc Malo:** Thank you.

My next question is for Mr. Keon.

When Mr. Russell Williams answered the last question he was asked, he said that all we had to do was invite generic medicine companies to work together on getting the regime to work. Will you follow Mr. Williams's suggestion? Is the Canadian Generic Pharmaceutical Association prepared to collaborate with patented pharmaceutical companies?

**Mr. Jim Keon:** Each company must decide if it wants to use the current legislation. It's clear that, in Canada, the legislation is complex. Other companies know what happened in the Apotex case and, for now, they have decided that it's not worth their while to try to use the legislation.

As I said, our companies already export generic medicines to developing countries, but it is currently too difficult to try to use this legislation and to obtain a licence authorizing the export of patented medicines.

[*English*]

**The Chair:** Thank you, Mr. Keon and Monsieur Malo.

Mr. Keon, I have you here as a witness for the Canadian Generic Pharmaceutical Association, but then you said "our company".

**Mr. Jim Keon:** I meant our companies that I represent in the association.

**The Chair:** Okay, so it was in the translation. I apologize.

All right. Now we're on to Mr. Van Kesteren for five minutes.

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

And thank you, witnesses, for appearing—those on the video as well.

This is a very complicated piece of legislation. I know there's a lot of emotion running very high here, and understandably so: we see the death and the devastation in the continent of Africa.

All of us would certainly like to be effective in whatever we decide on, and with that in mind, it has become apparent with the different groups we've spoken to that this has to be a concerted effort. This has to be a global effort. This has to be something we all participate in.

I want to direct my questions...and I have a few, for Mr. Plummer at least.

Sir, I want to ask what you think are currently the best ways for drugs to get to Africa. Can you give us some detail on how this government is expanding and supporting its efforts to Africa?

● (1235)

**Dr. Frank Plummer:** My experience is largely limited to Kenya, and there drugs are procured through the global fund and its processes.

In terms of what the Canadian government is doing, its contributions have primarily been financial, to things like the global fund, and organizations like GAVI, to help in their efforts to make medicines and vaccines more widely available.

My own expertise in this area is relatively limited.

**Mr. Dave Van Kesteren:** How do you feel about Canada's focus on getting drugs into Africa? I guess that's the question I'm asking. Should we support legislation like this? Is this the solution, or should we support current efforts of India and perhaps the U.S.?

**Dr. Frank Plummer:** Well, from my understanding of the situation and listening to the witnesses, I can't really speak to flaws in this area; it's not my area of expertise. But obviously many countries around the world have similar legislation that hasn't been accessed.

My understanding is that antiretrovirals are readily available at the moment. That may not be the case in the future, but currently they are readily available through systems like the global fund.

**Mr. Dave Van Kesteren:** We haven't spoken much about the Gates Foundation, but again, collectively, if we were to combine our efforts with organizations such as the Gates Foundation, contributing to providing the most vulnerable with the treatment and medicine they need, is that a direction we should be looking towards as well? Is that something we need to examine more?

**Dr. Frank Plummer:** Yes. I would say that we need multiple mechanisms, and the Government of Canada is doing that. The Gates Foundation contributes to the global fund, to GAVI, to other similar multilateral bodies, and I would think we should continue to do that.

**Mr. Dave Van Kesteren:** How much time do I have?

**The Chair:** Two more minutes, Mr. Van Kesteren.

**Mr. Dave Van Kesteren:** I'd just like to make a statement. I think it's something that's very important.

There's a misconception in this place as well—you and I have talked about that, Mr. Chair, on different occasions—that we're driven by big business and big money. There was some interesting legislation that was passed in this government, the Federal Accountability Act, that limited all of our funds for our campaigns and the money we collect as politicians to get re-elected, quite frankly. I say that because that's really important. We will oftentimes be visited. We had the pharmaceuticals and we had the generic people here today, all very good people, and they all have very good interests at heart, but ultimately we want to do what's right for Canadian society.

So when we attack legislation like this, we can do so with an open framework, because we have to operate on the rule of law, as a society, and governments that do that will continue to grow strong, they'll continue to grow wealth, and subsequently, they can help those less fortunate. So we have to keep those things in mind.

Maybe I could get a comment. I guess what I'm trying to get from my panellists is this. What's the best thing we can do as Canadians? What's the best area we can put our efforts into to get the greatest impact to help this crisis that continues to develop in the continent of Africa? If somebody wants to jump in and just make a comment, feel free.

**The Chair:** Mr. Keon.

**Mr. Jim Keon:** I would reiterate in part what others said today. We're here reviewing this particular piece of legislation, CAMR, and suggested amendments to it. We generally support the bill, subject to the one clarification.

In terms of medicines, that's what the companies that I represent make: they make generic medicines, good-quality medicines from Canada, approved by Health Canada. They can contribute more to the international situation. Whether it's the Gates Foundation or the global fund, if generics are available for important medicines, then the dollars in the global fund and the Gates Foundation will go farther. I think it's complementary, so I would encourage the committee to look very seriously at this bill and look at passing some of these amendments.

● (1240)

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

Mr. Jenner, did you have a comment on this? We only have about 30 seconds, anyway.

**Mr. Andrew Jenner:** Yes, thank you.

From my perspective, and certainly from a Geneva perspective, the global fund is a fantastic mechanism in order to facilitate medicine procurement. Because of its massive purchasing power and the scope of operations that it does, it makes sure that virtually all the medicines it procures have gone through safe and efficacy measures, for example, using the WHO pre-qualification process. I think that is where a real focus can happen. When we think about access, sustainable access, to medicines, I think the global fund is certainly one of the most successful options.

Thank you.

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

Mr. Plummer, go ahead.

**Dr. Frank Plummer:** Canada has been a leader in research on understanding epidemics and on prevention technologies. I would like to see emphasis on that, both on prevention with simple strategies that are available now and on HIV vaccines and microbicides.

**The Chair:** Okay. Thank you, Mr. Plummer.

Now we're on to Mr. Masse for five minutes.

**Mr. Brian Masse:** Thank you, Mr. Chair.

That's why this bill is so important, because it actually facilitates the strengthening of the global fund and the ability for the global fund to be used more comprehensively. This bill would accomplish that through the increased competition and making sure there would be strength out there for that competition.

I would like to ask Mr. Taubman a quick question. Mr. Taubman, you mentioned the WTO and that it would require another country or member to make a charge against Canada if someone felt that we're having intellectual property violations. Is that correct?

**Mr. Antony Taubman:** Yes, that's correct. We don't have any process that the WTO, as such, initiates. We're simply the adjudicator, if you like, in the event of a dispute.

**Mr. Brian Masse:** How often does that happen, not necessarily to Canada but among member states?

**Mr. Antony Taubman:** Of course, the rules of grievance of the WTO cover many fields of trade, and intellectual property is just one component of them. There have been over 400 disputes altogether, but there have been less than 30 concerning TRIPS or intellectual property as such. Canada in the past has been involved in two of those disputes, but this has been spaced over 15 years, so it's a comparatively rare occurrence. We've only had one such dispute in the last five years, for example.

**Mr. Brian Masse:** If there is a dispute between a compliant country and another country—I guess the one that is charged—it has an opportunity to correct matters if it so chooses before it goes to any official proceeding, hearing, and adjudication. Is that correct?

**Mr. Antony Taubman:** Most certainly. It's a requirement of our members, that if any country has a problem with another country's system, to enter into consultations beforehand anyway. If those consultations aren't successful, then there is a possibility of what we call a “panel proceeding”, which over time may result in a finding that the relevant law is not consistent with WTO obligations. Then what results is a recommendation that the law be brought into line with WTO obligations.

There is then, in legal terms, a “reasonable period” for the appropriate amendments to be made. There is a process of consultation, a process of fact-finding, and, on rare occasions, an actual determination as to whether the law is compliant or not. Then there'd be a reasonable period—typically 12 months or thereabouts —to bring the law into compliance.

● (1245)

**Mr. Brian Masse:** Thank you very much, Mr. Taubman.

That really debunks the Chicken Little theory that we have about how the sky is going to fall if there is a challenge and a violation, and we've heard that so often with this bill.

Madam Akugizibwe—I hope I'm getting that right, and I apologize if it's wrong—could you please outline how important it is for the drugs to be procured without having to negotiate first with the country coming forward? There seems to be a pattern in the past of some intimidation. We've seen that in Thailand and in other places. Can you highlight what it means for agencies?

The other thing too is that there seems to be a kind of paternal suggestion or a choice of either/or, that the infrastructure is not there, so we can't just send it over there. Can you talk a little bit about those two things, please? I think if we have this bill moving forward, it has a little more flexibility. It also allows groups and organizations even outside the global fund to be able to target specific areas where there is good cooperation.

**Ms. Paula Akugizibwe:** Yes, I think removing the necessity for a country to first express intent to procure from a Canadian company will certainly cut through a lot of the inhibitions, as I mentioned.

First, the tender process is the process through which a company decides which company it wants to procure from. So it's a bit irrational for countries to be required to express interest in a particular company if no other company is able to offer. So I think if that requirement is removed from this legislation, as you say, it will give companies more flexibility. It will also give them flexibility to respond to countries' needs as they change over time, and having a maximum quantity that a company is able to provide for a particular country is also not always a realistic thing for a country to do, if the epidemic changes significantly over the time in which the licence has been granted.

With regard to what I refer to as a false dichotomy, because that's really what it is, between infrastructure systems versus availability of medicines, I really think the two need to go hand in hand. One of the things we have seen is that clearly the ARV treatment, especially in southern Africa, contributes significantly to strengthening health systems, to strengthening infrastructure.

So it's obvious that if we don't have infrastructure, the drugs themselves cannot achieve their full potential, but it's really clear that without the drugs, there's very little we can do with the infrastructure. For someone who is living with HIV in southern Africa, the difference between life and death is really whether they have affordable medicine they can get access to in order to live. I think one of the things that discourages many governments from making the investment in infrastructure is not knowing whether they will be able to afford the treatment that will go with the infrastructure over the next five years or 10 years, especially with the threat to generics that we are currently experiencing.

I would emphasize that the role of access to affordable medicine is really what triggered the greatest degree of progress in the HIV response over the past decade, and it needs to be sustained.

**The Chair:** Thank you very much.

Now on to Mr. McTeague for five minutes.

**Hon. Dan McTeague (Pickering—Scarborough East, Lib.):** Thank you, Chair. Thank you, witnesses.

Mr. Keon, very quickly to you.

It would appear that you have a very significant, involved, cumbersome process by which you get applications, by which you have to negotiate with the brand-name holder, understandably. Except for the provision you referred to as far as ensuring there is absolute certainty and approval from Health Canada, you've suggested you would support the legislation. I'm wondering if you could give us an example specifically of where quantity and time may have a lot to do with the fact that no generic would dare try to reproduce what happened in Rwanda.

**Mr. Jim Keon:** I think generic companies are businesses. They look at developing products, typically as patents expire. They have a timeframe for that, and with this bill, you'd be looking at developing a product or a developing country market, not a Canadian market, not a U.S. market, not a European market, at an earlier point.

What I'm saying is they would need to develop the product as Apotex did, to do the testing, to get approval from Health Canada, and as the speaker from South Africa has said a couple of times, the system is all backwards. They have to do that before they can go to a country and indicate they have the capacity to provide the product. So for a developing country to come to Canada or Apotex or Teva or anyone and say they'd like them to bid on a particular product, that is a very backward process, as I said. They don't have the right to do that. They would have to start that process. It's going to take some time to develop the product, to get approval, let alone to negotiate the licence with the brand company.

So I think it's very important that the companies have a clear right under this legislation, if it's going to be effective, to make a product that will get a licence, and if they follow the rules on where it's shipped, etc., and diversion, that they can continue to make the product. Then we'll have a much greater chance of having products made under our legislation.

● (1250)

**Hon. Dan McTeague:** Perhaps Mr. Jenner or, Madam Akugizibwe, you could give us an explanation.

Mr. Jenner, you suggested the number of patients now being helped has grown significantly. I'm wondering how you square that, sir, with the 8,000 people who die every day in Africa directly or indirectly as a result of AIDS, tuberculosis, malaria, etc. What are your member organizations doing to specifically address the issue of second-generation needs for drugs to address these problems, and more specifically, pediatric drugs?

**Mr. Andrew Jenner:** Thank you very much for the question.

I think there are a lot of different issues that come out of this particular discussion, but if I can, I'll address the number of concerns. When you think about the need for developing countries in relation to access to medicines, I don't think we are here talking about primarily access to patented medicines. I think if you have a look at the research done on the ground, access to any medicines is a problem in any of these places. I attended a presentation in Geneva by the World Health Organization that highlighted that poverty remains a significant problem. If you cannot afford to buy the cheapest generic, buying generic or patented medicines is particularly problematic. The other problem they mentioned specifically in relation to this problem is access to clean water.

So all of these things feed into the general health and well-being of the individual people. The call, as has been mentioned significantly, is that governments really do need to pay attention as to how much money they are putting into their health budgets. If governments are not willing to put in sufficient amounts to guarantee access to the most simple non-patented generics, then it would be a very significant challenge for them to get access to generics of patented versions of medicines, because these are not cheap medicines, by and large. They still have some costs. They are cheaper, but there is a cost associated with that.

That is why I think it is important for us to think about the generic access to medicines debate rather than simply looking at a very small subset of the tools available. Compulsory licensing has been proven in some countries to be a short-term fix. It's not seen by many as being a sustainable solution to the access to medicines problem and access to medicines debate. I mean, I can submit for you for the record the massive expansion of our industry efforts in relation to access to medicines. I think I've submitted a short statement on that, but I can give you a little bit more detail on the rapid expansion of the effort that our companies are putting into achieving access to medicines. Simply—

**Hon. Dan McTeague:** Mr. Jenner, I'm sorry, my time is very brief, and I appreciate that—

**The Chair:** It's actually up, but if you want Madam Akugizibwe to answer, then we'll have her answer.

Paula, I know all the members want to be able to pronounce your name properly, so if you could just begin with that and then answer the question, we'd really appreciate it, because we'd like to respect that.

● (1255)

**Ms. Paula Akugizibwe:** Sure. It's “Akagizeebway”.

**The Chair:** “Akagizeebway”. Thank you.

**Ms. Paula Akugizibwe:** “Akagizeebway”, yes, phonetically. It's quite long.

In response to the question, I think we need to recognize also that we have made tremendous progress with regard to access to HIV treatment, but the number of people who are still in need greatly outreaches the people who have actually accessed treatment. So if you're looking at the figures of people who are dying daily from HIV, TB, and malaria, they're shocking, but it would be a lot worse in absence of the progress that has been made.

I agree that access to medicines in general is a challenge in most countries in the region. Underinvestment in health is a challenge, and it really underpins a lot of these problems with getting medicines to people who need them the most. But I think we need to recognize that this doesn't take away from the need to ensure that medicines are affordable.

What we've seen also with the funding crisis that I mentioned earlier is that where in the past people were guaranteed they would get the HIV treatment paid for by government, because of funding constraints now, that guarantee does not exist in many places. You are finding people having to pay for ARVs out of pocket. In that case, the price of the drug on the shelf in the pharmacy really is the most determining factor in whether someone accesses the treatment or not.

So just in terms of crucial...rolling out HIV treatment has been one of the most vital ways that we've strengthened supply to management systems in the region, and additionally, the platform that HIV activism has created has had ripple effects across the drug management system. We are seeing prosecutions happening, we're seeing reorganization of organizational structures in countries like Swaziland, recently this week, for example, to improve the way the drugs flow. That is a direct result of HIV treatment advocacy. So instead of trying to say that we can....

Okay, I'll leave it there.

**The Chair:** Thank you. We're way over time, and we just have a couple of minutes.

Mr. Wallace, it looks like you have about four minutes. I'm sorry.

**Mr. Mike Wallace:** Thank you.

My colleagues are happy that my time is limited.

**Voices:** Oh, oh!

**Mr. Mike Wallace:** There you go. I might be the last speaker before we go line by line on this, and I want to thank my colleagues around the table for dealing with this issue. I was one of the members on the government side who voted for this bill to move forward to committee. I've been very clear with the folks who have come to see me in my office that it was to be given to committee so we could have a discussion on the issue.

I frankly don't believe it will ever pass in its present form, but that doesn't mean it is not an issue we need to resolve. I don't really have a question for Mr. Schwartz, but I want to thank him for his description. It was very clear. I think we've heard from a number.... It's like anything in the law; that's why there are always lawyers on both sides of the table.

There is some risk here. I don't necessarily agree with Mr. Masse's approach that just because there are no penalties, we can go ahead and do something and then fix it after. I think that would be a bad message for my children, and it is for the Government of Canada. So I'm not buying into that.

I do have two questions, and maybe Mr. Jenner can answer one of them for me. What's bothering me most is that we've heard that there are a number of these CAMR regimes all over the world. There are 30 or 33 of them, and none of them seem to be working. Since he's representing an international organization, does he have any comment on why they're not working at present, or is there something we should be doing from an international perspective that we haven't heard yet to make these regimes...?

**Mr. Andrew Jenner:** Thank you very much for the question.

I think there are 54 WTO members who have actually implemented the paragraph 6 decision, and 27 of those are the countries of the EU. I think it's worth bearing in mind the context that if countries aren't implementing CAMR provisions, they cannot be utilized.

I think in relation to the countries that have done it—I think I referred to that in the comment I made some time ago, and certainly you might find that true here—the cost of generics from developed countries is significantly higher than is the cost of generics from somewhere like India, for example. That's something we need to be aware of, and that's something we need to bear in mind. The idea behind the August 2003 decision was that we are going to use an existing system that is based upon national experiences and established processes that are in place, but we are going to use this old system in a new way.

That has great advantages, and for some there can be some perceived disadvantages, but that is essentially what the system tries to do: it uses an old system in a new way. In response to the question about why we haven't seen mass use of it, I think there are other ways you can achieve access to medicines, but if you think about how long the provision has actually been there, it's not actually been in place for that long. If we were to do any form of legislative review, you'd have to look at a significant period of time and numerous cases before you could reach a conclusion that there was a problem.

Now, I think in relation to India, they have implemented protection for patent products since 2005. Previous to that, it would not have been necessary to issue compulsory licences for export. Now, there may be, in years to come, situations in which India would take advantage of their system as those new patent medicines are generally going through the regular due process in India, and then generics may wish to copy them upon request from a country.

I think that any review of any legislative process—by the EU or Canada, for instance—is far too premature in relation to how young this piece of legislation really is. As I have said, it is based upon established legal practice, which is why we have the number of provisions—there is article 10, if you want to see the EU regulations—that are in place that people will understand and people can use. From our perspective, these are reachable requirements; they are not burdensome. For those generics who are involved in this area, I think going through the process is not overly cumbersome, but I don't know that there is significant evidence to support that.

Thank you.

● (1300)

**The Chair:** That will have to be the final word on this today.

Members, please remember that at our next meeting on Thursday there will be clause-by-clause consideration. We will have officials here. Please, if possible, make sure that any amendments you're going to propose will be in by tomorrow at noon so we will have time to correlate them. As well, there is a steering committee meeting at 10 a.m. on Thursday.

That concludes our meeting. The meeting is adjourned.

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