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Chair

Mr. David Sweet

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● (1100)

[*English*]

The Chair (Mr. David Sweet (Ancaster—Dundas—Flamborough—Westdale, CPC)): Good morning, ladies and gentlemen. Welcome to the 39th meeting of the Standing Committee of Industry, Science and Technology.

One thing I should point out, particularly to the visitors—I think most of the regular members have gotten used to this—you'll see there are two clocks with two different times. We'll be operating from this clock, which is most representative of the Hill time that is displayed on our BlackBerrys. So in case you're wondering, we're actually on time.

Mr. Peter Braid (Kitchener—Waterloo, CPC): BlackBerry time is the right time, Mr. Chair.

Voices: Oh, oh!

The Chair: Absolutely, I agree, and that's why we're following it. Thank you for that intervention, Mr. Braid.

Now I'd like to introduce the witnesses for today. We have in front of us Richard Elliott, who is the executive director of the Canadian HIV/AIDS Legal Network. Welcome, Mr. Elliott.

We also have Mr. Don Kilby, who is the president and founder of Canada Africa Community Health Alliance.

I understand both of you have opening remarks. Is that correct?

Mr. Elliott, we'll go to your opening remarks first, then we'll have Mr. Kilby's opening remarks, and then we'll go to our traditional rounds of questions.

Mr. Elliott, please begin.

Mr. Richard Elliott (Executive Director, Canadian HIV/AIDS Legal Network): Thank you, Mr. Chair, and thank you to the members of the committee for the opportunity to appear before you today. Thank you as well to the committee for actually studying this bill, because I know that was something that has been in some question.

I want to draw your attention to the material that we have provided. You will find a copy of our brief. I think it's been provided to you already. I will come back to it in the course of my remarks, and I hope it will address many of the questions that you have. I hope to answer those questions over the course of the next two hours.

By way of introduction, I'm a lawyer who has been working on HIV-related legal issues for 18 years. For the last nine years I've been working intensively on questions of international law, including WTO law, and access to medicines, including doing graduate work on the subject.

This is also a personal issue for me, not just an intellectual one. I was born in Africa and raised there for a significant portion of my life. I have worked for many years in Africa with various partner organizations responding to the global AIDS crisis.

The organization for which I work, the Canadian HIV/AIDS Legal Network, has been working on this particular issue for nine years now, from back when the World Trade Organization members were adopting a declaration recognizing that they needed to do something about the barriers that patents pose for developing countries in getting access to affordable medicines, to the discussions that led to the drafting of Canada's access to medicines regime—enacted unanimously by Parliament in 2004—to organizing international consultations with experts from around the world on pharmaceutical procurement and intellectual property law, to a consultation that we held earlier this year with the UN Development Programme. This consultation generated some analysis that will be coming to you as an additional submission on the question of whether the proposed reforms in Bill C-393 are compliant with Canada's obligations as a member of the World Trade Organization.

This is an issue on which we have a fair depth of knowledge. It is perhaps not a surprise, therefore, that the brief we've submitted to you is some 50 pages in length. However, I hope it will be of use to you, and I want to draw to your attention the appendix in particular, because I think it will be a particularly useful reference for you.

As you know from reading Bill C-393, the bill makes a number of amendments to two pieces of existing legislation, the Patent Act and the Food and Drugs Act. Of course, it's hard to get the real sense of what the bill does unless you track all of the changes that the bill would make to the existing statutory provisions. To make it simpler, we've done that for you; in the appendix to our brief you'll find the relevant sections from the Patent Act that constitute Canada's access to medicines regime and the relevant provisions in the Food and Drugs Act. We have tracked onto the existing text of the law the additions and deletions that Bill C-393 proposes to make so that you can actually read it through in its entirety and see what the final text of the law would look like with these proposed amendments. I find it's much easier to have the discussion when you can see what we're actually talking about, and not in isolation.

I'd like to cover four areas in my remarks today, if I could: I'd like to tell you what CAMR is supposed to do, but I won't belabour that too much, because you know that; I'd like to say what CAMR has actually done, but that won't take very long, because the answer is "not much"; I'd like to tell you what Bill C-393 would do; and I'd like to tell you what Bill C-393 would not do, because there is a fair bit of misinformation circulating, including some of what you heard from government representatives last Thursday at your meeting, claiming all sorts of things about what Bill C-393 supposedly would do, and that information is not in fact correct. Let me speak to each of those four, if I could.

Briefly, what is CAMR, the access to medicines regime, supposed to do? The fundamental purpose of CAMR, as reflected in the discussions that preceded it at the World Trade Organization, is to help developing countries make effective use of compulsory licensing. That is the terminology negotiated by World Trade Organization members, including Canada. They are to make effective use of compulsory licensing in order to address public health problems by getting more affordable medicines.

The goal, stated by WTO members themselves, is to promote access to medicines for all. This arises out of discussions at the WTO in 2001, nine years ago, in which WTO members, including Canada, explicitly recognized that patent restrictions on medicines are a barrier—not the only barrier, but a barrier, and an important barrier—to affordable medicines getting to patients in developing countries.

● (1105)

Very specifically, one of the things WTO members recognized was that when you have patent restrictions in a place like Canada, where there is the capacity to make generic medicines and to supply them to developing countries that don't, you need to have some mechanism to get around that; otherwise it's patent infringement for a generic manufacturer here to be producing and exporting these generics. So WTO members set themselves the task of coming up with a mechanism that would get around that barrier, and that was a decision adopted in 2003, about which you've heard a great deal and which is really the central piece of WTO law relevant to any discussion of the existing CAMR and the reforms proposed in Bill C-393.

The purpose of CAMR—to implement a mechanism so that developing countries can make effective use of compulsory licensing to get generic drugs from Canada—is aimed at harnessing the power of competition. We're operating within a market paradigm here and we're harnessing the power of competition in the market to drive the prices of medicines down for developing countries. That is the purpose, and that in fact is what we've seen globally, that when countries have had the ability to get generic AIDS drugs, the prices of those drugs have dropped from over $10,000 U.S. per patient per year to $100 per patient per year now for some regimens. That's an order of magnitude of difference, and of course it makes feasible the task of putting people on life-saving treatment.

Because of this we have now seen four million people with AIDS in the developing world getting life-saving medicines in just a matter of a few years. This has only been made possible because there was competition in the pharmaceutical marketplace for those countries, and generic medicines were available at much lower prices. None of that would have been possible if the limited moneys made available for donor aid to buy medicines had to be spent to buy $10,000 courses of a treatment per patient per year, as opposed to $100 per patient per year.

That's what CAMR is supposed to do. Second, what has CAMR actually done?

As you know, it's been more than six years since CAMR was enacted by Parliament, and in that time, after a lot of work by a number of NGOs, after the commitment from one generic manufacturer, we have seen one drug leave this country to go to one country. That's tremendously significant for us, because it shows that we can do things, that we can make a difference. But I think it would be wrong to conclude that it somehow proves that the current access to medicines regime works. That result came about, as I said, because of years of hard work by various NGOs. It came about partly by chance. It came about because of conditions that are not easily replicable in future, and the one generic manufacturer that had made a commitment to NGOs, that is, to Doctors Without Borders, to try to make this regime work has said it will not attempt to do it again because its experience so far has not been encouraging.

However, that same company has also publicly committed that if the legislation is streamlined the way Bill C-393 proposes to do, the first next step for them would be to make a pediatric version of this drug. Access to AIDS treatment for children living with HIV falls way behind access to treatment for adults with HIV—who already are less than half of the people who need treatment now, and who will die without it. That's why it's so important that we have pediatric formulations of antiretroviral drugs, because 80% of children who are born with HIV will die by the age of two if they do not get medicines.

There are some medicines out there now that are being used to treat children. In many cases, they are not particularly user-friendly. If you can imagine that you're a grandmother caring for several orphans, some of whom are HIV-positive, it's not a particularly helpful way to make AIDS treatment available to children if you have to periodically get to a clinic—if they have the medicine at an affordable price—to get a syrup that you have to carry back to your home, where you may or may not have refrigeration.

If you could instead get something in simple tablet form, that is, something much more portable and not requiring refrigeration for storage, or in the form perhaps of something dispersible so it could be administered more easily to infants, then you would really be trying to get into the real world of getting medicines to people in a form that is easily usable. That's something that we can do if we fix this legislation. It would be a first next step, and then we would move beyond that with more medicines from generics at lower prices.

So what CAMR has actually done so far is relatively little. I don't think we can say that one drug to one country in six years is a success, given the need out there and given what was promised.

What would Bill C-393 do then?

● (1110)

You will have heard and seen in our material that we have described the core of Bill C-393 as putting in place what we call a one-licence solution.

Under the current legislation, every single drug order for each individual country requires a separate process of trying to get a licence to supply that country with a fixed quantity of medicines. It also requires that you know ahead of time the country and the specific quantity of medicines that you want to supply. In CAMR's experience to date, that has proven to be one of the most significant stumbling blocks, and it explains in part why it took two and half years to get to the point of having the first licence issued. I can explain to you why that is.

Our proposal in Bill C-393, which we fully support, is to change that process of licensing so that a generic manufacturer will get one licence, once, that will authorize that generic manufacturer to supply any of the eligible developing countries that are already recognized in the WTO law and in the Canadian legislation with the quantities of those medicines that developing countries will notify from time to time.

That will reduce the transaction costs of using the system. It would put generic manufacturers in a better position, because they can bid to supply multiple countries simultaneously, knowing that they already have the legal authorization in hand to do that. In the current process, they have to go into a bidding process individually with the different countries, without even knowing whether they'll be able to get the licence in the end to supply the drug, should their bid be chosen, because they will need to go through the current cumbersome CAMR process. Bill C-393 would simplify that and cut through that.

The Chair: Mr. Elliott, you're substantially over your time. I'll give you another minute if you want to wrap up.

Mr. Richard Elliott: Thank you.

Perhaps I could save the fourth part of my remarks—the question of what Bill C-393does not do—for the question-and-answer session, because I expect that I will get a number of questions about what it is claimed that Bill C-393 will do, and I would be happy to correct the record.

Thanks very much.

The Chair: Thank you, Mr. Elliott.

Now we will go on to Mr. Kilby. You have up to ten minutes for your opening remarks, sir.

Dr. Don Kilby (President and Founder, Canada Africa Community Health Alliance): Thank you very much for having me here. I will keep my remarks a little briefer than my colleague and make sure I stay close to time.

I'm a family physician, an HIV primary care physician, and as you've heard, I'm a founder of the Canada Africa Community Health Alliance, a small local volunteer-based charity based out of Ottawa working with partners in Africa to improve the health of rural African villages. There are about 150 to 200 Canadians a year who choose CACHA in order to volunteer on medical missions. They volunteer their time and underwrite the full cost of each mission, including the medications that we dispense free of charge and the medical supplies, as well as surgical supplies needed to enhance the level of care of our partners.

We work on a determinants of health model, and we believe that health is proportional to access to housing, secure food supplies, education, water, sanitation, transportation, employment, and personal security and freedom. We do not restrict our efforts to medical care only. We also support orphans and vulnerable children programs; build infrastructure, including a made-in-Canada floating dispensary; provide solar lighting in villages for students to study; drill wells; support microfinance; and support people living with HIV and AIDS. Given the recent reports on Canadian charities, we do this using at least 90% of all taxable revenues directly in the countries. This is a young organization, an organization that's only been around since 2002.

Today what I want to talk about is the whole issue of access to medications in resource-limited countries and the role Canada had hoped to play and could still play in order to contribute in a significant manner to the world's continued and growing needs for affordably priced essential drugs.

In 2003 I was here supporting legislation for Canada's access to medicine regime, and we believed at the time that it was the right thing to do and it was a good move. I will admit that also at that time, given the complexity of the regulations around securing a compulsory licence to produce, we seriously doubted that any drug under this regime would ever make its way from Canada to another country. We didn't criticize Parliament's efforts at the time but rather took pride in the fact that Canada was the first G-8 country to amend its national laws in order to implement the World Trade Organization's decision to allow generic versions of still patented drugs to be manufactured and exported under compulsory licensing.

Canada's leadership would bolster efforts in other countries to do the same, so that developing countries could have access to a steady supply of cheaper drugs available in a more competitive market. In the area of HIV, access to generic, co-formulated, triple-drug therapy available from India became the hope of nations in the scale up of treatments of AIDS in Africa. So in 2003 we had 400,000 people in low- to middle-income countries who received antiretroviral drugs. By 2005 we had 1.3 million, and by the end of this year, there will be 5.2 million people on antiretroviral therapy in resource-limited settings. In 2009 alone, there were 1.2 million new patients initiating antiretroviral therapy.

In 2002 at the International Aids Conference in Barcelona, we were all told it couldn't be done. I remember attending a presentation that was done by Médecins Sans Frontières, who were working on a project outside of Cape Town in South Africa, and a Harvard group in a project in Haiti. They had presented successful demonstration projects that we then used in order to replicate these thousands of times across Africa and the Caribbean.

At that time I remember a very heated discussion and a lot of criticism coming from the International Monetary Fund and the World Bank. It was said at the time that people in resource-limited settings would not be compliant with therapy, not as compliant at least as people in North America or Europe, that local governments could not put in place the infrastructures as well as the procurement and distribution systems necessary to get drugs to patients, that there were not the trained personnel needed to treat so many people, that the world could just not afford it, and that the business model was flawed.

● (1115)

To the credit of the G-8 leaders, at the insistence of groups like Médecins Sans Frontières and others, and the World Health Organization's global fund, and the bilateral U.S. President's emergency plan for AIDS relief, they committed to the goal of three million people in treatment by 2005.

So procurement processes were put in place, thousands of allied health-care providers were trained, clinics were built, testing programs and mother-to-child transmission strategies were expanded, as well as programs dealing with the social and economic fallout, including millions of orphans and vulnerable children. There are now home-based programs and local AIDS service organizations in place throughout all of the world today.

Essentially what we have been able to do is develop a comprehensive model of care many believed could never be built, and this in only a few short years. What was accomplished is nothing short of a miracle: 5.2 million people on treatment by 2010.

CAMR and other compulsory licensing programs should also have evolved during this time to ensure that we have a continuous flow of medicines at affordable prices. In all other areas, other than procurement of drugs, the concerted international efforts ensure today that all that needs to be in place to get medicine to people is in place.

CACHA is working with partners in Benin, Gabon, Tanzania, and Uganda, now since 2002. We concentrate our efforts in the hardest-to-reach populations in remote rural communities where there were no services for people living with HIV and AIDS. We help our local partners articulate needs, identify those infected through testing, and secure infrastructure necessary to treat people with HIV. And we secure this through strategic partnerships that are south-south, north-north, and north-south.

In Tanzania in three remote village areas we have seen our partners go from no HIV patients in care to more than 10,000 people in care in less than three years. Up until recently drug procurement and access has not been an issue. But this success is now being threatened in other countries, not only in Tanzania, by the limited supplies of affordable therapies.

The supply issues have nothing to do with getting drugs to local markets. The problem is procurement of cheaper, first-line therapies in sufficient quantities to treat all those who should be on treatment. Today, 5.2 million need to remain on treatment, and close to another 5 million need to be on treatment.

Canada's access to medicines regime should become a viable source of affordable medication available in a manner consistent with traditional procurement practices of purchasing countries that would allow these countries to ask for competitive tenders in order to ensure best pricing and timely delivery of product to market.

What we have in place is not meeting the desired goal. We have worked with government officials in two of the countries and we have examined with them the procurement mechanisms in both cases. And both countries have found that they are too cumbersome when other markets were available to them, despite their strong desire to purchase drugs from a North American generic company.

The other issue we have is that today, as people fail on therapy because of drug intolerance or toxicity, or compliance issues, countries now need to invest in newer drugs, second-line therapies, but these are at ten to fifty times the costs of first-line therapies. Health-care budgets in these countries cannot sustain such costs without significantly limiting the number of new patients who would access cheaper first-line treatments. Compulsory licensing, therefore, is needed even more today. It is needed to ensure an adequate supply of both affordable first and second-line treatments.

We can't rely on a system that's so encumbered by regulations. We need a system of compulsory licensing that is not time-limited, with no set limit on quantities to be purchased, and that can turn on a dime.

So CACHA supports a one-licence solution: one compulsory licence on patented medicine, regardless of quantity of medicine ordered or the number of eligible countries requesting the drug. Doing this will cost Canadian taxpayers nothing, beyond the international aid dollars we have already committed. And doing this will do nothing to reduce the profits of multinational pharmaceutical companies. There really is virtually no market for their patented drugs in developing countries, and without a market there is no real threat to their future or to the future of research and development in resource-rich settings like our own. In fact, CAMR royalties from otherwise non-existent markets would be paid to these patent holders.

● (1120)

This doesn't mean that these drugs that are produced in Canada that are destined for other markets would make their way back to Canada to be sold on the black market in resource-rich settings. We have enough processes in place in terms of the labelling and sanctions, and in fact if we look at our market and at that of our neighbours to the south, virtually all people with HIV and AIDS have access to drugs that are paid for through either private or public funding mechanisms. So enacting Bill C-393 will make the much-needed medicine more accessible and, through competition, also more affordable.

Thank you.

The Chair: Thank you, Mr. Kilby.

Now we'll move on to questions, starting with Mr. McTeague and the Liberal Party for seven minutes,.

Hon. Dan McTeague (Pickering—Scarborough East, Lib.): Thank you, Chair.

Witnesses, thank you for being here and for being very thorough in your presentation.

I had a question at the outset, because I was given a figure, and I'm not sure it's correct. For the daily mortality rate in Africa as a result of AIDS, indirectly or directly, does either one of you have a figure?

Mr. Richard Elliott: The most recent figure I've seen—and it may be a year or so out of date—is approximately 8,000 deaths a day from AIDS.

Hon. Dan McTeague: The bill before us, you readily admit, is not the perfect silver bullet or panacea, but you have said it's a step in the right and very important direction. You've both offered the one-licence solution.

I'm wondering why in all of this we didn't take into consideration the possibility of untangling the complex nature of these agreements between the patent holder and those seeking generic products to provide to Africa through compulsory licensing, and why the federal government wouldn't itself be the one administering, negotiating, and ensuring a streamlined process so that we could actually target the countries we wish to help. Admittedly we are not going to help all of them, but we could do a much better job at the one or two that we would pick. Has any thought been given by either one of you to the possibility of the federal government actually working with a brand-name company, and assigning a generic company then, if possible, to deploy the necessary medicines under a compulsory licensing regime?

● (1125)

Mr. Richard Elliott: In 2003-04, when the discussions were under way about drafting what is now CAMR, this issue did come up a few times in discussion. There was very little appetite to do that, it appeared, on the part of the federal government departments that were involved at the time, and I suspect that appetite is as little now as it was then, and perhaps for good reason. I think there is certainly a role for entities like CIDA to play, obviously in mobilizing funds and in drawing the attention of developing countries to the options that might be available to them to get lower-priced medicines, but this is fundamentally a mechanism that is about making the market conditions such that private actors—in this case generic drug companies—are going to see that it is worth their while because they will at least recoup their spending on this and make a small amount of profit, and about making it possible for developing countries to use this.

The idea is that the mechanism should be one that brings the purchaser and the producer together. I'm not sure you would necessarily improve the situation by sticking the government in the middle of that when you could actually just make that process work simply for the two parties instead of having the government as some sort of middleman.

Hon. Dan McTeague: I'm just curious. With regard to simplicity, we're talking about some fairly complex legal documents. I'm referring not only to the cumbersome nature of the legal requirements and hurdles that have been placed before a generic to be able to provide, such as in the case of Apotex in Rwanda, but also, of course, to the strategic problems of addressing multiple barriers to access in Africa. Governments are different from country to country. The ability to administer is also made more complex.

I'm just wondering, if we had one player, an impartial umpire who had an interest, as dedicated by Parliament.... On the road to good intentions, we all agree we should do more. The problem is that what we are pursuing has not worked, and we're not sure about CAMR being the silver bullet to overcoming some of these trial-and-error issues we have found ourselves in for which if it's not Canada it will be another nation.

Let me address something in the form of a question for both of you. It is going to be an important one, and I know my colleagues will ask this as well. As CAMR is currently written, there appear to be two prevalent concerns. There are obviously others, but one deals with the obligations and the possibility of trade sanctions under WTO. The second concern is about rushing into Africa medicines that may not be appropriately approved here in Canada. Could I have your comments on either of those, please?

Mr. Richard Elliott: On the first question, about compliance with WTO obligations, the proposals that are in Bill C-393 have been drafted with the expertise of people who know what the WTO law says, and very much taking that into consideration.

There is extensive discussion in our brief of this very point. It walks you through why it is that the provisions that are core to Bill C-393 are in fact compliant with the decision of the WTO General Council from August 30, 2003—which is the key instrument here—and with the underlying treaty, the agreement on trade-related aspects of intellectual property rights, TRIPS.

There are international legal experts who have been tapped to provide input in the drafting of this bill. I mentioned earlier that we convened a consultation of a number of legal experts earlier this year with the UN Development Program. We spent a day going through the provisions of Bill C-393, looking at whether these were compliant with the requirements of the WTO. The answer was pretty much yes.

There were one or two places—as you'll see in the report of that meeting, which is coming to you as soon as it's back from translation—where the experts said, “This is compliant with WTO. However, you could see that there might be some ambiguity here. So here is a recommendation about how you make a slight tweak to remove any question that this is compliant with WTO obligations.” That was the purpose of the consultation. We wanted to know if it was compliant with WTO, and if it's not, what we should do to address that. The answer was that it's compliant as is, but here are some things you can actually do to make it even better.

I think that will be useful for the committee's deliberations once you have it, and we'd certainly be happy to discuss the details there.

● (1130)

Hon. Dan McTeague: The medicine's part of it, the accuracy, the....

Mr. Richard Elliott: Yes, the second question, yes.

There is, I think, a somewhat simplistic mischaracterization of what the bill would do on this question of ensuring the safety and quality of medicines. The first thing I should say is, as an advocate for treatment for people, I want people to get good quality medicines. I don't want people to get substandard medicines. That would defeat the entire purpose.

The bill as proposed would preserve Health Canada review of any drugs that are being exported as one option, one pathway to ensuring that the product that is being exported is of good quality and is safe. However, it adds other pathways to achieving that objective, including for example the World Health Organization's pre-qualification program, which is actually supported in part by Health Canada with technical assistance. It was set up by the WHO as a program specifically to provide assurances to countries that the manufacturers and the products they were getting have met quality standards. That's why it's there. Many developing countries—

The Chair: I'm sorry, but the time is marching on, and again we're well over. Mr. Kilby, even though we're well over, did you want to comment on this?

Dr. Don Kilby: Just on the quality of the medications. As Richard has said, the bioequivalency of these drugs needs to be identical to what we have available to us here in Canada. The thing that we have when we're dealing with partners in Africa, now that we know that.... There's a great deal of trust in terms of the system that we presently have in place to ensure that quality, in comparison to the trust that there may be for the other drugs that are arriving to market today.

The Chair: Thank you, Dr. Kilby.

[*Translation*]

It is now the Bloc Québécois' turn. Mr. Malo, the floor is yours for seven minutes.

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

Good morning and thank you for being here with us for this first meeting with witnesses, with the exception of the officials who appeared before us last week.

Dr. Kilby, I understand from your testimony that, as of now, there are enough drugs for AIDS on the African market to meet the needs as expressed by your partners working in the field with the affected groups. But you are telling us that there could now be an access problem since the 2010 objective is to treat 5.2 million patients. That's what I understood from your testimony.

During our last meeting, we realized that India was an important, if not the most important, supplier of antiretroviral medications for African countries. Is it because India's production capacity is no longer sufficient to meet the demand that you feel problems could arise right now?

Dr. Don Kilby: That is correct. Up to now, 5.2 million people have started therapy. Our goal is to double that number so that people will be treated sooner. At the moment, people in Africa are not treated the same as people elsewhere. In Africa, they wait for people's immune system to be really compromised. We now understand that, if we wait for too long, even if we succeed in bringing down the person's viral load, the life expectancy will not be the same as if we had started earlier. So, to be fair, we would like people in developing countries to have access to treatment earlier.

That means that we would have to almost double the number of people being treated. But we have already started to see problems of access to the medication in Tanzania and Uganda, because suppliers are no longer able to provide the required quantities so that the medication is on the market on time.

● (1135)

Mr. Luc Malo: When you talk about doubling the numbers, does that mean the total will be 5.2 million or 10.4 million?

Dr. Don Kilby: There will be 5.2 million people undergoing treatment by the end of 2010, but there should be close to 10 million.

Mr. Luc Malo: According to you and your partners in the field, that would meet Africa's current needs, would it?

Dr. Don Kilby: That would meet the current needs. In other words, it will take a few years before we get to that point.

Having said that, we have a real problem today: can we continue to supply medication to 5.2 million people? Some countries have trouble buying the drugs they need.

Mr. Luc Malo: Will those countries make a request to the WTO, as Rwanda did in 2007? Are they planning on doing something like that?

Dr. Don Kilby: Absolutely, they are already doing that. To obtain their medication, they are going through the same systems they have already used.

That said, we must open up the field for two reasons. First, there will be more markets, which could meet the needs of the African market. Second, by having more competition on this market, we will be able to further reduce the price of treatments.

Mr. Luc Malo: I see that Mr. Elliott wants to make a comment. I am going to ask my last question and then turn over the floor to you.

What you are telling us is that the drugs available on the African market are currently still too expensive.

Dr. Don Kilby: If we want to double the number of people getting treatment without raising the final costs—since these medications are largely paid for by the Global Fund program or by PEPFAR—we have to reduce the price of medications even further.

Mr. Luc Malo: So are we trying to take care of twice as many people with the same budget?

Dr. Don Kilby: Yes, without having to go back to G8 to ask once again for twice as much money.

Mr. Richard Elliott: I just wanted to add one thing. We must remember that the drugs from suppliers in India are generic drugs and these are the drugs we are currently using to treat patients with HIV. For the most part, they are first-line antiretroviral drugs. That is why we now have 5.2 million people undergoing treatment. Most of them are taking the generic drugs from India.

In the last few years up to now, we have noticed an increase in the number of people who have had to change their regimen to follow a second-line antiretroviral treatment. Under Indian legislation, these products have had patent protection since 2005. So it is not possible to get these drugs in generic form because it is not possible to produce a generic version under Indian legislation. So the drug access crisis will become worse in the future since costs will go up, especially when there is no competition on that market.

Mr. Luc Malo: What is the estimated number of patients who will need this second generation of drugs?

Mr. Richard Elliott: That is going to change, isn't it?

Dr. Don Kilby: When we look at the North American or European market, nearly 20% of people must follow a second-line treatment. But there is another problem: we should have never chosen the first-line treatment we chose from the beginning. It was well intentioned in the beginning, but today we realize how toxic this treatment is. When a patient follows this treatment for two or three years, the toxicity level is very significant. We will now have to replace the most commonly used molecule, which is available around the world, with something safer.

● (1140)

Mr. Luc Malo: So, in the long run, all the patients who must be treated will have to be treated with second-line drugs. So, we are talking about 2 million people if we take 20% of 10 million.

That really is the key issue, isn't it?

Dr. Don Kilby: Exactly.

Mr. Richard Elliott: But it is not a static situation. It is dynamic.

Mr. Luc Malo: Yes, of course. I am well aware that, even if we treat people, the pandemic is not contained.

[*English*]

The Chair: Thank you, Mr. Malo. Your time is up. I'm sorry, the clock always marches on.

Mr. Braid, for seven minutes, please.

Mr. Peter Braid: Thank you very much, Mr. Chair.

And thank you to both of our witnesses for being here this morning. This is a very important discussion, and I appreciate your perspectives and contributions to this conversation.

I wonder if I could start with you, Mr. Kilby. As we know, Canada was the first G-8 country to develop a regime like CAMR. Are there other similar regimes to CAMR now in place in our G-8 partner countries?

Dr. Don Kilby: Not to the extent that Canada has, but I think Mr. Elliott could comment.

Mr. Richard Elliott: I can speak to that, because I think it's a legal question more than a medical one. There are a number of other jurisdictions that have adopted a version of CAMR. They've put in something in some form, in regulation, legislation, state directive, what have you, that implements the WTO decision from August 2003.

None of those have worked because none of them have actually done it well. They also suffer from different deficiencies. Canada has its own deficiencies, and some of those are shared by other jurisdictions. Some of the other jurisdictions have other deficiencies.

Nobody has got it right yet, but I think Canada could.

Mr. Peter Braid: To take that one step further, are any of those other jurisdictions with regimes similar to CAMR G-8 partner countries?

Mr. Richard Elliott: Yes.

Mr. Peter Braid: Which ones?

Mr. Richard Elliott: The European Union has adopted a regulation that is applicable throughout all the EU member states. The Netherlands is not a G-8 country, but it is a high-income country. Switzerland was drafting one. And then the others would be countries like India, Korea, and so on. They're not G-8 countries but they are countries that have a significant generic production capacity.

But the EU is probably the G-8 stand-in, if you will.

Mr. Peter Braid: Have any of those advanced countries then, G-8 or not, supplied any developing countries with HIV/AIDS medication through a regime like CAMR?

Mr. Richard Elliott: No.

Mr. Peter Braid: So only Canada has done it, albeit only once, to Rwanda. No other advanced country has done it.

Dr. Kilby, if I could explore a little further, you mentioned that today, in 2010, over five million individuals in Africa are receiving HIV/AIDS medication. I think the way you positioned that was that compared to previous years that demonstrates tremendous progress. It's certainly something we all celebrate.

With respect to those 5.2 million people who are currently receiving medications, could you explore a little further exactly where those medications have come from? Through which mechanisms have those medications come, and from which sources and source countries?

Dr. Don Kilby: Most of the medication in circulation that people are using is from India. They're the generics.

There's one particular co-formulation of 3TC, d4T, and nevirapine that is very popular. Most of that has been brokered, and the pricing as well has been brokered, by the Clinton Foundation. The Clinton Foundation has worked tirelessly, and it continues to work tirelessly, to ensure the lowest possible price to the greatest number of people. Most countries have benefited from that type of brokerage.

But the virus is not consistent throughout the world, and certainly in west African countries there are certain strains of the virus that do not respond to this fixed-dose combination. They're probably the hardest hit in terms of the cost to procure medications for their population because they need to go to the more expensive second-line therapies. As Richard said, they're going from $150- to $160-a-year regimens to about $1,000-a-year or $2,000-a-year regimens, for the same budget. They can treat only a fraction of the number of people they could have treated if they had a regimen that was affordable.

● (1145)

Mr. Peter Braid: The reason the cost is going up is that we're going from first- to second-line therapies.

Dr. Don Kilby: It is because we're going to the second-line therapies.

Mr. Peter Braid: Okay. When you say that the Clinton Foundation has brokered many of these arrangements, exactly what do you mean by brokered? What has the role been?

Dr. Don Kilby: The role has been an arm-twisting role, if nothing else, in terms of showing up at the generic company in India and negotiating markets for the product. It negotiates between the countries that wish to procure and India, which wishes to export. It negotiates between the parties and negotiates on behalf of the countries to get the price reduced. The initial price of this formulation was considerably higher. It was about $600 per year. Now it has dropped considerably.

Mr. Peter Braid: One of the concerns and arguments we've heard is that even if we make CAMR work more effectively, at the end of the day, developing countries want to buy their drugs and medications as cost-effectively as they can. It sounds as if that's what's happening now. The main source is India. I know that we've touched on this already, and Mr. McTeague asked this question as well, but just help us understand that a little further. If at the end of the day, India, China, or even the U.S. provide less expensive generic medications than Canada does, how can we compete or be involved in this process?

Mr. Richard Elliott: Thank you.

I think it's important to remember that in the one instance when, despite the flaws in CAMR, it was actually made possible to get a medicine out the door, the price the generic manufacturer offered Rwanda was competitive. It was 19.5¢ per tablet, which was the same price on offer from the Indian generic manufacturers. We have to remember, as I was saying before, that although India has been an incredibly important source of supply of generic medicines—it's been the pharmacy of the poor—the Indian generic industry does not have the capacity as it is now to supply all of the generic medicines the developing world needs. The Indian generic industry is actually under some significant pressure.

I mentioned earlier, in responding to Mr. Malo, that in 2005, as a condition of being a WTO member, India changed its patent law so that it now grants patents on pharmaceutical products. So those first-line, first-generation antiretroviral drugs that have been key in putting 5.2 million people on treatment are being supplied because they come from a time when there was no patent protection in India on those medicines. The reason the price is now shooting back up for the second-line drugs we're talking about is that those are not available, for the most part, in generic form, and they won't be available easily from Indian manufacturers, because they now have the patent barriers at the Indian end of things.

So the situation for the potential competitors of Canadian generics is changing. Canadian generics can compete, in some instances. If we actually made it simpler and less costly to use this mechanism and let them actually line up multiple contracts with multiple countries at one time under one license, you could actually then achieve economies of scale that would let them bring down the prices of medicines further, because they could get their ingredients more cheaply. Their production lines would be cheaper to run per unit, so you would be more competitive.

All of these factors are in play, and it seems to me that they all point us in one direction, which is to make this thing simple and easy to use, because we'll be able to compete.

● (1150)

The Chair: Mr. Braid, I'm sorry, but you're well over again. I'm trying to be as fair as I can be and allow the answers to go on and yet have some semblance of order on the time.

We'll go to Mr. Masse now. We'll try for seven minutes.

Mr. Brian Masse (Windsor West, NDP): Thank you, Mr. Chair, and thank you to our guests here today.

We had rather interesting testimony from the departments the other day. In their deck and presentation and in another document that was provided as a briefing, they were saying that on one hand, the proposals in C-393 would enter us into a trade challenge and maybe threaten investment in Canada. There would be a series of other problems. At the same time, it wouldn't work.

It didn't make any sense. They were making both claims.

One of the points I wanted you to maybe comment on is that they say here:

> There is no evidence that changing CAMR will result in more developing countries using the regime to import drugs from Canada rather than continuing to purchase low-cost drugs from other sources.

We were just talking a little bit about that with Mr. Braid. I'd like you to talk a little bit about the Apotex situation. The reality is that we have generic companies in this country that are world-class successful and would increase jobs if production actually increased. Can you comment on that, please?

Mr. Richard Elliott: I can, and I actually think there are two experts who have also made a written submission to the committee, addressing some of these very specific points, two economists who have studied the pharmaceutical sector quite intensively.

One thing to say in response to this claim that there's no evidence that changing CAMR would actually make a difference is I think it's fair enough to say that we won't know until we try. If we never try, then certainly it will never make a difference. So why don't we give it a try? What's to lose? The worst possible scenario is that nothing changes, it makes no difference. That would be terribly disappointing, but at least we tried.

The best possible scenario would be that in fact our predictions are right. By making this simpler we would see it used again. We have a company that's already committed to using it to do a pediatric version of a drug. So that's a positive outcome.

To me that doesn't seem to be a reason not to try. There seems to be every good reason to try. It does seem odd to say it's not going to work and yet somehow it's going to have all of these negative consequences of exposing us to a risk of a trade challenge or undermining incentives for research and development.

I think the experts who have given you submissions, who have studied the pharmaceutical sector, are quite clear that there's really no correlation here. I think Dr. Kilby even alluded to the fact that making it easier for us to supply generic medicines to developing countries where these are not significant markets for the brand-name companies in the first place is somehow going to undermine their decisions about investing in research and development.

Those are not the markets that are driving their research and development decisions now. That's why we have what's called a 10/90 gap. That's why we have neglected diseases in the world, because these are poor people in poor countries. They're not the ones that a pharma wants to spend money researching and developing medicines for.

To say, then, that making it easier for those countries to get lower-cost generics is going to undermine the R and D decisions of the brand-name companies.... The two are not really connected. I think anyone who looks at the economics of the industry will tell you that.

What would happen, if we get a good outcome from this, is that you would in fact have a certain sector of the industry lining up contracts to supply medicines that are not being supplied to anybody now, which would, yes, lead to jobs. It would lead to royalty payments to the brand-name companies on those contracts.

It seems to me that it's actually a win-win situation all around.

Mr. Brian Masse: Dr. Kilby, do you have anything to add?

Dr. Don Kilby: I agree completely with what Richard is saying.

Mr. Brian Masse: One of the other interesting aspects that has been proposed is that there would be this conspiracy theory that we're undermining the transparency, the policing mechanisms, and the accountability.

You have to come up with some scenario where there would be a generic producer that would illegally act and then provide medicines to people with another country, and then a pharmaceutical company would oppose that, and then take us all away to a WTO challenge. So they would be protesting the treatment of people, I suppose, with these drugs, which would be an interesting public relations issue.

I asked the department for the evidence that a generic company would be out there to basically produce these drugs and then have them back into the commercial market, creating some type of scheme.

Can you maybe provide some highlight about how when the dispersement takes place what properties are in place to make sure the medicines actually get to their intended targets—the children, the men and women—and how difficult the scheme would have to be to basically produce these drugs and then reroute them through commercial means away from people, which once again for the generics would be quite a significant public relations scandal?

This is a theory that's been proposed to us by the departments.

● (1155)

Mr. Richard Elliott: There's the on-the-ground part and then there's the legal part about CAMR. Maybe we could split it up.

Dr. Don Kilby: I always find it amusing to have this discussion, even with my colleagues and friends from the pharmaceutical industry, that a product that's a generic product, produced in this country, that's labelled differently, that looks different, that's totally, for all intents and purposes, different, first of all, is going to make its way back to a market of people—we're talking HIV/AIDS in this case—who really have.... We don't have an access issue in this country. We've put in place everything that needs to be in place to ensure that people are either covered privately or through public plans.

So what we're saying is that these drugs would then somehow come into our provincial formulary programs and be dispersed somehow through our pharmacies at a cost of nothing because our patients don't pay. I don't know where this is going to come back into Canada. And the same thing holds true for Europe, where many of the programs are similar to those in Canada.

But more importantly, access to drugs for HIV/AIDS in the United States, where we keep saying that there'd be a real potential for abuse in that market, when we're talking HIV/AIDS, really, every single person with HIV/AIDS in the United States of America has access to free antiretroviral drugs. I have a patient who just moved this week, who is so happy he's going to get his free meds there, because as a businessman up here in Canada he had a co-payment with his insurance company of 20%.

I think that's a bit of smoke and mirrors, in terms of having these drugs come back. I think there's real potential for these drugs to travel across borders in resource-limited settings. I think that's a true possibility that could exist, but not back to northern markets.

Mr. Richard Elliott: I would differ slightly with Dr. Kilby about the perhaps overly rosy picture regarding access here to medicines being perfect. In the U.S. there are barriers to access, but not necessarily the patent barriers.

I did want to specifically speak to the legal aspect of preventing this kind of diversion from happening. And while most of our brief is focused on this question of compliance with WTO rules, there's actually a section toward the end that talks about this misconception, that somehow Bill C-393 is going to remove all the safeguards against this sort of diversion of medicines. It actually preserves safeguards that would require different labelling, different packaging, colour, shape, and so on of medicines that are being exported. And if that's not clear to you in the bill now, then let's work on making that clear, because we want those safeguards to be in place.

The other thing I want to say is that under Bill C-393, provisions that are in the current law are preserved that require generic manufacturers to disclose the quantities of medicines that they're shipping and to which countries. That information has to be disclosed to the patent holders; it has to be posted on a publicly available website. You have to disclose that not only to prevent the diversion of medicines but also so you can calculate the royalties that you have to pay to the brand-name companies.

So those things are all in there as important parts of the mechanism. They're preserved.

The Chair: Thank you, Mr. Elliott.

Thank you, Mr. Masse.

We're going to move on to our second round now, and back to the Liberal Party.

Mr. Rota, for five minutes.

Mr. Anthony Rota (Nipissing—Timiskaming, Lib.): Thank you, Mr. Chair.

Thank you for being here today.

If we can go back to the first-line and second-line medication, we're actually increasing costs, and one of the keys here is to keep the expenses down. Can you explain to me, and I'm not quite clear on this, how the one licence system will actually help in a developing country?

If it's too expensive at one level, even if it's cheaper than what you're paying in developed countries, how do we get it to the people who need it? You mentioned I think it was $150 versus $1,000, if I'm not mistaken. All of a sudden $1,000, you mentioned bringing it down to $650. It's still more than they can afford.

What worries me, and I'm trying to figure out where the benefit is, is if we come up with something that says okay, we'll allow the drugs to go in, they're still too expensive. There's no use on the ground. How do we get around that? I'm not quite clear on the benefit at the tail end if it's still too expensive.

● (1200)

Dr. Don Kilby: Right now, a lot of the arrangements that are made for some of these second-line therapies are that they are being acquired from northern markets and not from generic markets. Many of them are being offered at reduced prices within an environment that protects the patent of those drugs.

What we're looking for in terms of having these being able to be offered and genericized, and mixed and matched as well, is to create ease of therapy, because many of the molecules available today are not co-formulated. You don't have three drugs in one pill.

When you are able to make something generic, make it available, you can then take something from one company that's patented in one company and take something from another company that's patented with the other company and put them together in one pill and make it a lot easier for patients to take.

The other piece is now you are in a more competitive environment as well, because if this formula is repeated through different markets where these compulsory licensing agreements are in place, then we can actually have these components of therapies produced generically and be much cheaper for the end users, to the purchasers.

Mr. Anthony Rota: One of the issues that's come up quite often with people I've spoken to who are quite familiar with the area is that it's nice to say we're going to provide inexpensive medication, which is important, but the infrastructure in certain countries isn't developed. You're bringing it over there or you're allowing it to get there and it sits stagnant. How do you deal with something like that?

Dr. Don Kilby: I think, again, that's in my mind another.... I'm not saying it's not challenging and more challenging to go into a market where you don't have the same types of processes and systems in place as we have in developed countries, but as I said earlier, it's not short of a miracle to think of what people said could not be done. They said that 400,000 was about the max that we could get people onto therapy, because of all of these things that were not in place. The reality is we have 5.2 million people, and we have clinics all over, all across the map.

If you look in Tanzania, where there were two sites available, one in Dar es Salaam and one in Moshi, where you could be treated for HIV in 2002, you now have over 60 sites by 2010. We could not have done that in our own country. By being able to get the drugs to people, to get drugs into the country and to transport those medications to all those sites, some of which are in rural isolated areas, we have been able to show and demonstrate that it's possible to get drugs to people and to get people on drugs.

We may have a model of care in this country that says a prescription needs to be done by a physician, but treatment algorithms have been developed for developing countries that allow all kinds of health care providers to be able to follow simple algorithms of treatment so that we have the necessary people who have been trained throughout and over the last eight years to be able to do that. So it's not an argument for me.

Mr. Richard Elliott: I would just add that if we have all of that infrastructure in place, but that infrastructure can't actually purchase medicines at an affordable price, what is it giving to patients? The two actually are not mutually exclusive; they need to go hand in hand. So this is about dealing with the pricing issue, and then we need complementary action to build up the infrastructure where it doesn't exist. But as Dr. Kilby was saying, there have been tremendous strides made in building up infrastructure, although we still need more.

The Chair: Sorry, Mr. Rota, the time is up.

We'll go to Mr. Braid again for five minutes.

Mr. Peter Braid: Thank you, Mr. Chair.

I just want to continue some of the threads of our conversation here.

Mr. Elliot, I realize we're dealing with Africa, but I want to come back to India just briefly. You mention that patent law in India is evolving. Does India have a regime similar to CAMR today, and if not, will it need one as that patent law evolves?

● (1205)

Mr. Richard Elliott: Thank you. That's an excellent question.

Because India now grants patents on pharmaceutical products—where it did not before 2005—in order to produce and export a generic version of a drug, you would need a mechanism like CAMR. In 2005, when India made the changes to its Patents Act to introduce patents on products, it also included one paragraph in the Indian Patents Act, section 92A, that is basically supposed to be the equivalent of CAMR under Indian law.

It's interesting, because that provision has not yet been tested and it's a mirror image of the Canadian problem. With CAMR we have far too much red tape. Things are just gummed up with unnecessary restrictions and laborious processes, and so on.

The unfortunate deficiency of the Indian legislation, in my view, is that it doesn't provide enough detail. You have one paragraph that doesn't actually provide the operational guidance that's needed. So, for example, where the Canadian legislation, to its credit, does define very clearly what the royalties are that have to be paid by a generic company to a brand-name company in the event of a licence being issued, which is a hugely important feature for the generic companies because they said all along that they need certainty about what the cost is going to be at the end, which makes sense from a business perspective, the Indian legislation has no such specificity about what the royalty is that has to be paid. You can be sure that the first time someone tries to use the Indian legislation it's going to be months or years of litigation in the Indian courts, arguing over what's the appropriate royalty that has to be paid here. That's one of the reasons there's this big question mark over whether India is going to be able to continue supplying generics to the developing world.

So, yes, it's there on the books, but I think it suffers from deficiencies just like the Canadian one does, although a different deficiency.

Mr. Peter Braid: Very good.

Now a question about health reviews: on the HIV/AIDS medications that are working on the ground today in treating those 5.2 million people, through which health review mechanism were those medications tested and ensured that they had adequate efficacy and were safe? Were they through the country mechanisms, or the World Health Organization mechanism that you mentioned, Mr. Elliott?

Mr. Richard Elliott: It would depend on the country, but most of the drugs, most of the generics, for example, that are being used to treat people are being WHO pre-qualified. That's why WHO set up that mechanism, and most developing countries that are purchasing medicines are requiring that there be that WHO pre-qualification for any medicines they purchase.

Mr. Peter Braid: Dr. Kilby, I just want to move on to another topic if I could. You addressed an earlier question concerning the possibility of drugs in larger quantities being shipped to a developing country and coming back. In your mind, you see that as a very low risk. I did hear you say, though, that one possibility or concern was drugs leaking across borders on the African continent, for example. So could you just tell us a bit more about that and why you're concerned about that? Ultimately, the purpose of this mechanism and these drugs is for humanitarian purposes and not for commercial purposes or to be diverted. So could you speak a little about that?

Dr. Don Kilby: The reality is that the borders are a lot more porous than the borders we have here, and people do cross borders all the time.

I know when we work, for instance, in Benin, and we offer services to people from Benin, there are lineups of people who come from Togo. They cross the border and come to get free medication, free dental care, or whatever we have to offer. That's the kind of porousness that's going to happen. And it happens already today. One country may have a procurement process in place, and even though the drugs technically are destined to the people of that country, there are people who filter through that and get medication, for instance, in Kenya and get back into Uganda, where there's a shortage of supply.

Mr. Peter Braid: So is it more a case of people travelling to where the medications are being administered, as opposed to the medications being diverted? That would be the concern.

Dr. Don Kilby: Exactly.

The Chair: You're virtually out of time.

Now on to Monsieur Malo.

[*Translation*]

Mr. Luc Malo: Thank you, Mr. Chair.

Dr. Kilby, you said earlier that the funds available for buying medicines in the affected areas, by which I mean developing countries, come from two different sources. In fact, you mentioned two, but perhaps there are more than two. I would like to get the big picture. Right now, how much money is on the table from the various sources that are available to purchase antiretroviral drugs for the countries you work in?

● (1210)

Dr. Don Kilby: What happened in Africa specifically is that the continent has been divided, meaning that the countries who make multilateral donations are responsible for some countries, or parts of countries, and the Americans are responsible for other parts of the countries. So, where we are working, the programs are sometimes subsidized by the Americans and they are the ones who buy the drugs, and, other times, the drugs are bought through programs under UNAIDS and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

I don't know anymore what the total sum is and how many billions of dollars we are talking about. I think we are at, for the two—

Mr. Richard Elliott: The Global Fund is around... It depends on each country's contribution.

Dr. Don Kilby: The amounts have gone down this year. We were aiming for about $10 billion. The Americans put in $3 billion. So we're talking about a market of around $13 billion today.

Mr. Luc Malo: Is the $13 billion used to buy drugs only?

Dr. Don Kilby: It is for the whole infrastructure development program and for drugs. It is for everything.

Mr. Luc Malo: How much of that goes to buying medicines?

Dr. Don Kilby: I don't know how much.

Mr. Luc Malo: As Mr. Braid said earlier—and Mr. Masse mentioned it in his question—there is the whole issue of traceability. And this does not necessarily have to do with whether the medication will be returned, but whether it will be distributed elsewhere for commercial purposes. So a drug diversion problem would arise. When the officials appeared before us last week, that is one of the aspects they drew our attention to, saying that Bill C-393 reduces traceability, or does not allow for the traceability of drugs in order to ensure that they are really going where they are supposed to.

Mr. Elliott, in your presentation, you were challenging some of the negative arguments against Bill C-393 made by the officials last week. In your opinion, their warnings to us were not justified. Could you perhaps provide more details on the topic? Could you explain why, in your opinion, officials responsible for the smooth operation of Canada's Access to Medicines Regime, that is the officials responsible for making sure that vulnerable populations have access to drugs, would want to put up roadblocks, so to speak? Why would they be against improving the program, which is designed to ensure that vulnerable populations get the help they need?

Dr. Don Kilby: First, Canada is not facing any problems because of a plan that does not work. Actually, if we had a plan that did not work, there would be no risk of diversion or of other problems surfacing. But if we want a plan that works better in terms of drug supply, we will have to face some risks. No one can say that we won't be facing any risks. The officials' job is to make you see the potential risks Canada would be exposed to if we were ever to review the legislation in order to make it easier to supply medicines.

I feel they're doing a good job. Their job is to tell you where the risks lie. But I am not sure whether these fears will turn out to be true. However, I am sure that, if people around the world stayed home without doing anything just to avoid taking risks, we would be in big trouble. Anyway, that's not the main goal of Canada's Access to Medicines Regime.

● (1215)

Mr. Luc Malo: Could you tell us your opinion, please?

[*English*]

The Chair: Monsieur Malo, we're actually way over time. I was just allowing Mr. Kilby to finish the answer to that question.

[*Translation*]

Mr. Luc Malo: I am simply asking him to give us his opinion.

[*English*]

The Chair: We'll have to wait until next time.

Thank you, Mr. Kilby.

Now to Mr. Van Kesteren for five minutes.

Mr. Dave Van Kesteren (Chatham-Kent—Essex, CPC): Thank you, Mr. Chair, and thank you both for coming here this morning.

Mr. Elliott, I want to congratulate you for your obvious passion. You've obviously done much work here, and I think it must be very frustrating for you to see all these lives being lost. I wanted to make mention of that.

Did you say there were 8,000 people a day who die?

Mr. Richard Elliott: Yes.

Mr. Dave Van Kesteren: Have I got my math right—is that 2.5 million a year?

Mr. Richard Elliott: Yes. These are figures that come from UNAIDS.

Mr. Dave Van Kesteren: Is that only Africa, or is that worldwide?

Mr. Richard Elliott: That's worldwide.

Mr. Dave Van Kesteren: That's worldwide.

Mr. Richard Elliott: Africa is the most heavily affected continent, so the bulk of those deaths are happening in Africa, but it's not only Africa.

Mr. Dave Van Kesteren: But the majority are in Africa.

Mr. Richard Elliott: Yes, 90%

Mr. Dave Van Kesteren: I'd like to talk about some of the other illnesses, and maybe, Dr. Kilby, I could talk to you about this.

Do we use this legislation, this vehicle, for illnesses like malaria? How many people a year die of malaria? Do you have those figures?

Dr. Don Kilby: The numbers in Africa are even greater than the number of people dying of HIV and AIDS, if you look at the straight numbers. In reality, malaria today in Africa is a function of immunity, because when people are immune-compromised, they are more susceptible to malaria and to deaths due to malaria. If we didn't have HIV and AIDS, what would be the deaths due to malaria in Africa today? It would be far lower than it now is. It's the same thing for diarrhea, the same thing for other illnesses, and tuberculosis in particular.

Of course, the global funds program is not restricted to HIV and AIDS and procurement for HIV and AIDS; it's also for malaria and tuberculosis.

Mr. Dave Van Kesteren: And not because AIDS isn't a horrible disease, but malaria is the number one killer, is it not, across the globe? Isn't it the number one killer of infants?

Dr. Don Kilby: No. Diarrhea's probably the number one killer of infants, but malaria is the number one killer. Again, it's my HIV education piece here. People don't die of HIV virus; people die of pneumonia. So we could say the same of Africa. People don't die of HIV virus; people who are HIV-infected die of malaria and tuberculosis. And in the case of tuberculosis, when people are immune-compromised, they activate their tuberculosis and become people who can spread tuberculosis to others as well.

Mr. Dave Van Kesteren: I guess my question is not to minimize the tragedy of AIDS, but is this legislation helping those who are suffering? Not everybody is infected with AIDS among those who die. I think we have polio just about eradicated. I think Afghanistan and maybe one more country in Africa.... But is this helping, or are we using it as a vehicle to stop that tragedy as well, against other diseases, like, as you said, diarrhea?

Dr. Don Kilby: For sure, in terms of the global fund, and in terms of the program that would access most this type of legislation in order to get the drugs—

Mr. Dave Van Kesteren: Are they getting the drugs, though? Are they getting the drugs?

Dr. Don Kilby: They would not only look to break patent, if you would, for HIV, but we do have a serious concern with malaria as well, because the drugs that are not patent-protected are really inferior drugs to those we have available to us throughout the world. So what I use when I go to Africa to protect me, under patent, is not available to people in Africa unless we use this type of legislation.

Mr. Dave Van Kesteren: So why aren't we doing that? Why aren't we doing that as well with malaria? Why aren't we getting generic drugs put into place for those who suffer from malaria?

Dr. Don Kilby: They are doing that as well.

Mr. Dave Van Kesteren: Are they, and in all countries?

I guess, Mr. Elliott, you wanted to jump in.

Mr. Richard Elliott: This legislation is not doing that as it stands because, as we were saying, there's been only one use of it, and that has been for an AIDS drug to one country. So we can't say this legislation is doing anything. This legislation could do something, because the legislation, as it stands now, is not limited to only AIDS drugs. It's really important to underline that, because this was an issue that was central in the WTO negotiations that led to the instrument that then led to CAMR.

There was a real effort by the U.S. and the European Union to say we're going to come up with a flexible mechanism so that you can export generic drugs to countries that need them, but there was a real push by them to say this is going to be only for HIV, TB and malaria, and possibly for other epidemics.

There was a really strong push-back, quite rightly, because what are we going to say then—"You're not dying of the right disease, so therefore too bad"? Are we going to say, for example, "We can get those medicines for cancer in the rich world, but we're only going to get AIDS medicines to you folks in the poor world?" That was simply unacceptable, and it is unacceptable. So at the end, the agreement among all WTO members was that this mechanism could be used to deal with public health problems.

They make explicit reference to HIV, TB, and malaria, because they are three big killers, but it's very clear that it's not limited to those diseases. And the current legislation is not limited to those diseases, although in practice it's actually hard to use it for anything else, which is one of the reasons there's a reform proposed that would make it easier for it to apply to drugs to deal with public health problems, because that reflects what the WTO intention was.

● (1220)

The Chair: Thank you, Mr. Elliott.

Thank you, Mr. Van Kesteren.

Now on to Mr. Masse for five minutes.

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

One of the interesting things about the bill....The department is very critical of it. Setting up the standards, it could be a runaway success. I guess a runaway success would be that we'd have a lot of different drugs that then would be exported, treating people and actually saving lives. It's kind of an interesting analysis of it. But they also painted the picture that Apotex in Rwanda was a success story.

You know, getting the drugs to those individuals, yes, that is a success. But the process wasn't. And they painted the picture that CAMR worked very efficiently in that, but CAMR requires you to do some work before you actually do your paperwork with it. Can you maybe go through that experience?

What I find kind of incredible about the department's attitude in this is that.... I asked them during a briefing that if they don't think Bill C-393 is a good bill, could they offer suggestions on how to improve it, and not one of the departments could offer one suggestion on that. I find that incredible, because if we don't change it, it's just not going to get used at all.

The hoops that were jumped through to get the Apotex Rwanda thing done.... Back in 2003, when we started this, there were warnings that it wouldn't work. But at the same time, when we had the final piece, we all said we'll put down our swords, stop fighting over it and try to make it work. Now that one success story is being used against fixing the system.

Can you provide some insight into the timelines of what happened in Rwanda?

Mr. Richard Elliott: Yes.

Mr. Brian Masse: Their own customer is now saying they won't do it any more.

Mr. Richard Elliott: Yes, I can.

I wanted to, before I forget, draw your attention to a document that you have in the materials we gave you. This is a briefing paper prepared by Doctors Without Borders—Médecins Sans Frontières—describing their experience of attempting to use the legislation, working with Apotex to get this drug because MSF had identified that they needed it.

This part of the story that MSF lays out in this brief walks you through the chronology. However, it stops in the middle of 2006 because MSF ultimately abandoned the effort to use it, after trying for about 18 months to get a country to come forward.

When we hear repeatedly that it only took 68 days from start to finish for this piece of legislation to work, to get this licence out the door, that leaves out of the story the entire months and months and months leading up to the point where finally a country did come forward. That's because the law, the way it's drafted now, requires that the country be known ahead of time in order to then move through the process of trying to get a licence. But that's not the full story if you just look at, "Oh, now we finally have a country, so we can start the process of trying to get a voluntary licence from the brand-name company, and if that doesn't work after 30 days, then we can try to get a compulsory licence to supply a fixed quantity of a drug for only two years", and so on.

All of the back story is left out of that narrative, about why this bill took so long to even have one successful use. It's because it created this kind of impediment where you made the use of it contingent upon knowing one specific country ahead of time.

That's why the one-licence solution that is in Bill C-393 would get around that problem, because it would say it's not contingent upon having one country identified ahead of time to get a licence. You get the licence and then you go out and actually bid to supply countries. If you're offering a good product at a competitive price—which you would be in a better position to do if this is simpler to use—then you can actually supply because you have the licence already to supply that eligible country.

So I would encourage people to learn what the experience was and where the stumbling blocks were encountered with the existing legislation, which is precisely what we thought they were going to be. I think we can then learn from that to make it work better.

● (1225)

Mr. Brian Masse: The bill also.... I want to touch on this briefly. There's been the suggestion that this is going to affect research and development, big pharma, that they would actually pull back funding from Canada. That's actually suggested by the department here, which is interesting. If the big pharma.... I don't care who it was, it would be a public relations issue, that they would actually punish a country for innovating and doing something different.

But they actually get a royalty. They will get payment out of that. Can you touch on that? They're not just going to watch their research and development and their thing be basically put on the Internet and thrown out there. There are provisions that protect. And second of all, they get a payment stream from the generics for that.

Mr. Richard Elliott: And they get a payment stream on sales that they are themselves not making now because their pricing strategy in developing countries is not one that makes it affordable for the vast majority of people who have to pay out of pocket for medicines. So those are unrealized sales for the brand-name companies now. If you create competition in those markets by allowing generics to get in there and compete with them and bring the prices down, they will be lining up customers that will be making sales to patients who were not getting medicines before and indeed paying royalties to the brand-name company on those contracts, which the law requires them to disclose.

The royalty scheme that's in the law now is based, actually, on a proposal that we put forward back in 2004, so that the poorer the country, the less developed the country, the lower the royalty payment should be. The maximum royalty that should ever be payable is 4% of the value of the contract. That was the standard that was used when we used to use compulsory licensing regularly in Canada to supply the Canadian market. So there's no reason that poorer countries should be paying anything near what we used to pay by way of a royalty when you're supplying a rich country market.

The Chair: Thank you, Mr. Masse.

Mr. Brian Masse: Thank you.

The Chair: Now we'll move on to Mr. Lake, for five minutes.

Mr. Mike Lake (Edmonton—Mill Woods—Beaumont, CPC): Thank you, Mr. Chair. And I thank the witnesses for coming today.

I was listening to Mr. Masse's comments, the focus on “Making CAMR Work”, and talking about what the officials said or didn't say before the last meeting. I guess I heard differently than what Mr. Masse was hearing. I heard the officials say it wasn't so much that CAMR wasn't working, it was more about the fact that there are other things that are actually working better.

I think back to the invention of the car. Obviously when the car was invented, people stopped using horses and carriages. That didn't mean horses and carriages didn't work; it just meant there was a better solution for moving people around. And eventually people stopped using horses and carriages.

In this circumstance I see that we have 400,000 people who were treated in 2003, 1.3 million in 2005, and it will be 5.2 million people by the end of 2010. We're making progress, largely because it sounds as though the global fund is being used to buy drugs from India. And for whatever reason, drugs are being supplied by India cheaper than they're being supplied by other countries, including Canada under CAMR. To me, the fact that the number of people being treated is going up as quickly as it is is a good thing.

The first question I would have is this. In regard to India, if it enacted its patent legislation in 2005, and if most of the drugs being supplied to Africa are coming from India, why has the number of people being treated with these drugs gone up from 1.3 million to 5.2 million? I just want a comment on those numbers.

Mr. Richard Elliott: Sure. Could I just offer a correction, or a clarification?

Mr. Mike Lake: Sure.

Mr. Richard Elliott: In the one instance when CAMR was used, it was not the case that the Indian generic manufacturer was offering it at a lower price. The prices were actually matched.

● (1230)

Mr. Mike Lake: Right. Generally, though, that's the case.

Mr. Richard Elliott: That's right. Well, we only have the one use so far of CAMR, and in that case it was a competitive price.

Part of the reason why we've seen the number of people on treatment go up is precisely because the generics have been available. The global fund money, for example, has been able to stretch that much further because you're paying 20¢ per tablet rather than five bucks a tablet. That's why we have 5.2 million people getting treatment now.

But as I was saying before, that source of Indian generics is now very much in question. And the tap is turning off because of these patent act changes. Now those changes were made in 2005. The drugs that were already being produced in generic form up to 2005 were grandfathered. So those are still able to be supplied. And because of where we are in the history of scaling up people onto AIDS treatment, it's still the case that the majority of people are on those first-line regiments, which are coming from Indian generic manufacturers.

What we're starting to see now, as Dr. Kilby was saying—and we will see more of it in the future—is that those first-line drugs are starting to fail for people as their virus mutates and develops resistance. So then they will need to switch onto second-line drugs and because India now has patent protection, these are the ones that are going to be patented in India. And so getting them in generic form from India is really very much an open question. We don't know how that's going to play out yet.

Mr. Mike Lake: One way or another, though. We don't know.

Mr. Richard Elliott: We don't know.

Mr. Mike Lake: Right.

Mr. Richard Elliott: We know it's going to be more difficult now to get generics from India. It may be impossible. Who knows? But there's certainly a patent barrier that has now gone up in India that will start to take effect.

Mr. Mike Lake: The flip side to that, though, is that with those changes in terms of the market approach to this, we may see—and you've spoken about that, Mr. Elliott—that it may lead to more people looking at CAMR as a solution as well.

I know my time is short. I want to get another question in here.

I'm looking at your brief, Mr. Elliott, on page 45. You talked earlier about the changes to the Food and Drugs Act. This was brought up as a concern by the officials the other day. I'll tell you, as I read through your brief here, I have some concerns.

The way that I see this, what you have crossed out is that the “act applies in respect of any drug or device to be manufactured for the purpose of being exported in accordance with the General Council Decision” and “the requirements of the act and the regulations apply to the drug or device as though it were a drug or device to be manufactured and sold for consumption in Canada”.

That's what you've crossed out.

What it's replaced with is: “No person shall export a product described in subsection (1) unless one of the following requirements is satisfied”. That's “one” of the following requirements. I look down the list there, and there are a few you've referred to that make some sense, but only one of them has to be satisfied.

Paragraph 38(3)(b) reads: “The drug regulatory authority of the country to which the product is to be exported has given written approval of the product”. That would mean, basically, that if Rwanda says that the drug works, then we can automatically export it to Rwanda, whether Canada would approve that drug or not.

Paragraph 38(3)(c) goes even further. It reads: “A drug regulatory authority of another jurisdiction has given written approval of the product and the government of the country to which the product is to be exported, in writing, that such approval is satisfactory”, so what paragraph 38(3)(c) says is that if Rwanda approves it, and then Tanzania says it accepts Rwanda's approval—

The Chair: You have to get to the point here, Mr. Lake.

Mr. Mike Lake: I know.

I have concerns as I read that. That changes things dramatically from where we are right now, which is that we say Canada has to approve it. It has to be approved as if someone in Canada were being treated.

The Chair: Respond as briefly as you can, Mr. Elliott.

Mr. Richard Elliott: I will do my best.

Let me first of all draw your attention to subsection 37(1) of the Food and Drugs Act, which is not changed by all of this. It is already the case in Canada that any drug that is made in Canada for export is not subject to Health Canada review; it is only in the case of a drug that is produced under CAMR for export that the requirement was made that Health Canada must review it. There was already, if you will, a demonstrated lack of concern on the part of the Canadian government for drugs being exported. However—

The Chair: You can do some cleanup on this, because the next round is Mr. Scarpaleggia. I'm sorry; I need to be fair to all members. Then we'll come back to the Conservative Party and others as well.

Go ahead, Mr. Scarpaleggia, for five minutes.

Mr. Francis Scarpaleggia (Lac-Saint-Louis, Lib.): Thank you, Chair.

I will give the remainder of my time to Mr. Rota. I'm substituting here, so I haven't been following the debate. You'll have to excuse me if my questions have already been asked or are too simplistic.

You mentioned that India was tightening up its patent regime. Do you anticipate that China will become a player in these markets at some point?

Mr. Richard Elliott: It could, and China is one of the countries that has what's called a “state directive” to implement the WTO decision from 2003, which was the basis for the Canadian legislation. China is one of the countries that has this.

It's very deficient, not the least because it's quite limited in terms of the diseases for which medications can be produced. Whether China will become a big player on this or not.... It's possible. I don't know.

● (1235)

Mr. Francis Scarpaleggia: You were talking about the Rwandan case. You said that the argument that it only took 68 days leaves out a lot of the struggle that occurred before those 68 days. You mentioned that having to identify a country first is a problem. Could you elaborate on that? I'm not sure I understand.

Mr. Richard Elliott: MSF made the commitment to Apotex that if Apotex developed this drug, this three-in-one fixed-dose combination that they needed in the field, they would seek to purchase it under CAMR from Apotex. Given the way the law is worded, in order for MSF to be able to do that, they needed a country to come forward and notify the WTO of their intention to do this and also of the quantity of the drug that the country expected to need.

The Chair: Mr. Elliott, just briefly, could you clarify? In the federal government we have so many acronyms, and I'm curious as to whether everybody's being respectfully silent and wondering what MSF is.

Mr. Richard Elliott: Oh, I'm sorry, it's Médecins Sans Frontières, Doctors Without Borders.

So in order for Apotex to then move forward to be in a position, legally, to sell it to MSF, they needed to be able to go to the brand name companies in Canada that hold the patents on those three drugs and say to them, "We would like you to voluntarily give us a licence to supply *x* quantity of this drug to this particular country". They then are required to negotiate for 30 days. If they cannot agree on the terms of a voluntary licence, then Apotex could apply to the Commissioner of Patents for a compulsory licence, and the commissioner, then, would order them to pay the royalty according to the formula in the current law.

But that 30-day window is really part of the problem, because you have to start that 30-day clock ticking if you want to run out the 30 days so that you're in a position to get a compulsory licence. That clock does not start ticking until you tell the brand-name company, "This is the specific country, and this is the quantity of the drug". So if you can't get a country to come forward ahead of time, you're stuck —

Mr. Francis Scarpaleggia: So you're saying it's very difficult to get the governments in some countries to come forward?

Mr. Richard Elliott: In some it is. MSF tried for 18 months—and it has a presence in various countries—and it ultimately abandoned the effort because it could not get a country to come forward.

Mr. Francis Scarpaleggia: You gave all the reasons why this bill is actually in the interests of the brand-name pharmaceuticals: they would get royalties; they wouldn't be cannibalizing their own markets, and so on. So why, in your view, are they so against the bill? What is the main reason? If it's actually a good business proposition for them, what's the sticking point?

Mr. Richard Elliott: Can I be frank?

Mr. Francis Scarpaleggia: Yes, that's what you're here to be—frank.

Mr. Richard Elliott: On one level it's greed—to be honest—and on another level it's a larger political agenda. And the larger political agenda, which I think has been on full display for decades now, has been that they want to impose on a global basis ever more stringent intellectual property rules, because that's in their interests as monopolists. I mean, that's in the nature of the scorpion that stings the frog carrying him across the river, right? Their interest is to protect a monopoly system as much as possible. And that's why they have first-world intellectual property standards globalized through the WTO.

The pharmaceutical industry and the entertainment industry were the major proponents of this agreement. That's very clear in the historical record. I'm not making that up. And they don't like the flexibilities that are in that regime, things like compulsory licensing, because if you're a patent holder, you're going to have a knee-jerk reaction against anything that allows your patent to be overridden, even if it's for a limited purpose. But WTO law is very clear that that is, in fact, part of striking the balance between protecting intellectual property and ensuring access.

That doesn't mean that they like it, so they will oppose—and they have opposed—every time developing countries either contemplate using compulsory licensing or issue compulsory licensing. And there is extraordinarily strong push-back: litigation, threats of trade sanctions, threats to withdraw the registration of new medicines—I'm talking about Thailand, South Africa, Brazil, and so on—over and over again, which is partly why, I think, countries have been reluctant to come forward, especially if what you're offering them is a flawed system that doesn't guarantee they're even going to get a medicine at the end of the day. Why would you stick your neck out and run the risk of this kind of retaliation when you're not expecting —

● (1240)

Mr. Francis Scarpaleggia: I don't know if there's time left for Mr. Rota.

The Chair: Officially there's not, but the Conservative Party did go over quite a bit.

So, Mr. Rota, do you have a brief question we can get a brief answer to?

Mr. Anthony Rota: Thank you, Mr. Chair.

I hope this is a quick question, and it actually ties into what Mr. Scarpaleggia was talking about.

The argument I've heard, as well, is that it's been only six years since CAMR has been implemented, and some would say it really hasn't had a chance to take full effect and it will probably start working once countries like India pull aside.

India, with the changes, with the WTO restrictions that have been put on it, or with the agreements that have been put in place, will likely pull aside. Realistically, can you think of any other countries that would take India's place? Will the changes prevent some of the problems that are occurring now, such as drugs not coming?

What concerns me is that we put the changes in place and nothing happens and we just keep going the way we are. I don't think that's the intent. What we want to see is actual implementation and actual availability of the medication.

Mr. Richard Elliott: Definitely. In our assessment, and in the assessment of those who've tried to use the current system and the experts who have looked at it, if we make these changes, we dramatically increase the chances of it being used again to get medicines out the door.

I don't think it's premature, after six years, and I don't know how many avoidable deaths, to say the system is not working. We have to accept the reality that one drug to one country in six years is not what was promised; it's not what it should be.

This was supposed to be an "expeditious solution": those are the words of the WTO members themselves. That's what they wanted to come up with. We haven't got it there, but we could.

The Chair: Now on to Mr. Lake, for five minutes.

Mr. Mike Lake: I want to follow up again, if I could, on the last line of questioning.

Mr. Kilby, I want to come to you with a similar question to what I asked Mr. Elliott. But I first want to lead in by saying that your testimony and what you've talked about with respect to building capacity and the things your organization is doing sound phenomenal. It sounds like exactly what is needed, based on conversations I've had with people who really care about this issue.

Let's be honest: we all want the same thing. We're sitting around this table and we have witnesses coming and arguing both sides of a piece of proposed legislation and we all want the same thing. We all want more help going to people in Africa to solve this significant problem, the number of people who are dying, not only of AIDS, but of all sorts of things that are completely preventable. People dying of diarrhea is completely unacceptable. We need to take steps to address those things.

Could you lead off in that context? Again, commenting on the numbers: 400,000 in 2003 to 5.2 million by the end of 2010 is significant progress.

We're obviously using other means than CAMR to make that progress. We heard in the testimony at the previous meeting that there are several things that are working, and that is a big reason CAMR is simply not being used. It's not necessarily that it's not working, it's just not being used because there are other alternatives.

Again, what was the number of people who are not getting treatment who need to be getting treatment? Can you remind me?

Dr. Don Kilby: Double.

Mr. Mike Lake: Double the 5.2 million. Are you saying double the number are not being treated, or is double the total number of people who need to be treated?

Dr. Don Kilby: Who need to be treated.

Mr. Mike Lake: So we need to double the 5.2 million.

With the momentum we have, it seems if we continue on that track we will get there soon; it seems as though we will. There's been a tripling from 2003 to 2005, and there's been another tripling from 2005 to 2010.

Dr. Don Kilby: But we have a few problems now. One, again, is the issue that we're not funding the global fund today as we funded it a year ago in order to do this work.

With less funding to do double the work...first of all, that's not going to happen. The only way that countries that contribute to these multilateral agreements through the global fund are going to even be able to get value for their investments—because they will be asked to invest again in the global fund, especially as we have more and more people who are clamouring to be on treatment and who are not going to be able to access treatment.... The cost to our government and other governments around the world is going to be even greater, especially if we are prepared to pay 10, 20, or 30 times more in terms of the drug costs.

The human resources costs, the procurement costs, the transportation costs, and all the rest of it, we can keep in check. The one thing we're not going to be able to keep in check if we don't come up with some sort of easy procurement solution for these drugs to be available cheaper.... At the end of the day, we either give up and say this the best the world can do, or, especially if we say we've made a commitment to 5.2 million.... We know today that with the molecule available out of India, which most of these people are on, 30% of them have to come off that molecule within two years because the toxicities are too great for them to continue. The pain they get in their legs and their hands is too great. We won't talk about them getting fat atrophy and their faces looking wasted and everything else; we're just going to talk about pain.

For that reason alone, when we move to the next level, to that second line, if we can't get that second line to them at the same price we're getting the first line to them, or at least at a comparable price, we're going to have to back away from that commitment we're already made to those 5.2 million people, and say, “You know what, you were on therapy, but we can only afford to have three million in the world on therapy because the costs are too prohibitive”.

And with the global fund—and, Pep Pharm, because the Americans have come back as well, in terms of their commitments—we just can't afford it.

● (1245)

Mr. Mike Lake: The thing that concerns me is that while we want the same thing, we recognize there are issues. I think the issues you're talking about, the things we need to address, we can probably have a common conversation around, with agreement on many things. What we've heard from the experts—and keep in mind that the government experts who were before us at the previous meeting aren't partisan experts, they were people who were the experts under the Liberal government and they're the same people who are the experts under the Conservative government—from four different departments was that they were adamantly opposed to this bill, saying the bill would accomplish virtually nothing and yet would have untold unintended consequences. And that's very concerning to me as a member of Parliament.

Again I come back and I'd just like you to comment if you could on the health question I asked. Does it not concern you that under C-393 we would have a regime whereby drugs are being approved by a country in Africa and having no approval process subject to the same considerations that a Canadian using those same drugs would be subject to?

The Chair: If you'd like to answer that question—

Mr. Mike Lake: I'd like that question to go to Mr. Kilby.

The Chair: Okay.

Mr. Kilby, you can address that in your closing remarks. I'm trying to get through so I can give you both about two minutes for closing remarks.

[*Translation*]

Mr. Cardin, you have five minutes.

Mr. Serge Cardin (Sherbrooke, BQ): Thank you, Mr. Chair.

Good afternoon, gentlemen.

I believe there is a significant issue in terms of funding. Does the $13 billion you talked about in the beginning represent the total sum for AIDS or is it for all diseases, in terms of health care?

Dr. Don Kilby: That amount is for AIDS, malaria and tuberculosis.

Mr. Serge Cardin: What would you say Canada's contribution is to the $13 billion?

Mr. Richard Elliott: A few weeks ago, the Prime Minister announced to the UN what Canada's contribution was. I can't remember the exact figure, but I think it was five dollars per Canadian more or less. So you can do the math.

Mr. Serge Cardin: You forgot to say “only”.

We are talking about CAMR. Mr. Lake told us that the new bill would be pointless. And, to be honest, CAMR has not been very useful in the last six years. Overall, how does Apotex's involvement fit in the big picture? It is quite insignificant. We could say that it amounts to practically nothing. So, as Dr. Kilby was saying earlier, if we do nothing, if we don't take any risks, precisely nothing will happen and, therefore, there will be no major developments.

In addition, you confirmed that the patented drugs were second rate compared to the generic drugs and therefore, less effective most of the time.

● (1250)

Dr. Don Kilby: No, that is not what I said at all. Second-line drugs are just as effective, but more expensive.

Mr. Serge Cardin: Oh, I see. Earlier, you were talking about first-line and second-line. You were saying that we had to think about using second-line drugs in order to improve treatment. But I was talking about generic drugs versus patented drugs. There is a difference, isn't there?

Dr. Don Kilby: There is a difference in cost, but not in how effective they are, since they have to be bioequivalent.

Mr. Serge Cardin: All right.

I have met with pharmaceutical representatives who told me they were involved in a number of international projects. I am sure that you work with pharmaceutical companies. In terms of patented drugs, how could the pharmaceutical industry get involved more directly? You wish there would be a jump from 5.2 to 10.4 million people, but I don't suppose a lot of patented drugs are sold to these patients.

Mr. Richard Elliott: That's right. I will continue in English, if I may.

[*English*]

The majority of the 5.2 million people who are receiving HIV treatment now in the developing world are on generic medications because that's what has made it affordable. That's how we've made the progress Mr. Lake was referring to.

There is nothing now that prevents the patent-holding brand-name companies from selling in those markets, and there is nothing in CAMR and nothing in Bill C-393 that prevents them from doing that. The point of having a patent is you actually have the right to sell the product. In fact, you have the exclusive right to sell the product unless someone else gets a licence, which is what CAMR is supposed to do.

This is simply about opening up the field, allowing greater competition in those markets. When the brand-name companies have had to face competition in the developing world selling their products, we've seen that that is what has brought the prices of medicines down. We need to keep that dynamic going. That's the purpose of something like le Régime canadien d'accès aux médicaments.

[*Translation*]

Mr. Serge Cardin: Do you think that the companies selling the patented drugs could one day open up to international co-operation and to this market?

Mr. Richard Elliott: We haven't seen that so far. You would have to ask them.

Dr. Don Kilby: Absolutely nothing is stopping them, and each company has a specific program to ensure that their medicines get on the market at a reduced price, meaning a price that is different from the price in the north. Also, these companies have the exact same systems in place to make sure that the drugs will not go back north: here they have a different name, a different colour and the labels on the packaging are different.

The companies are already part of a dual system where the north pays more than the south. But the difference between the price of patented drugs and the price of generic drugs is so big that this is not an option for most markets where the drugs are needed.

The Chair: Thank you, Mr. Kilby and Mr. Cardin.

[*English*]

We're a little bit over our time and we just have a little portion of time left.

Mr. Kilby and Mr. Elliott, I'd like to have your closing remarks, and they are compliments of Mr. McTeague, who decided to give up his time in order for you to have some closing remarks.

If we could keep it to two minutes, Mr. Elliott, and then two minutes for Mr. Kilby for any closing remarks you'd like to make, please.

Mr. Richard Elliott: Thank you.

Let me just address two points quickly, to get back to the question that a few people posed.

The first point is the issue of diversion of medicines, which of course we don't want to see happen. Dr. Kilby put it very well. We have to take some risks here. The legislation preserves the measures that were already negotiated and in place to mitigate the risk, to minimize the risk of diversion happening, and, let's not forget, that we cannot let the perfect be the enemy of the good here.

We have not had a significant problem with diversion, for example, of the donated discounted brand-name drugs that have been provided in these countries because they are using the same sorts of mechanisms that are provided for here for generic drugs. That has not been a significant problem.

That is not to say never say never. Should there be at some point a shipment of medicines that gets diverted, let's say if 99% of the shipment got through and we saved hundreds of thousands of lives because of it, if one shipment went missing, that is a price worth paying. But we have mechanisms in place that are there to prevent that from happening. Let's not overstate the risk there and use it as an excuse for not fixing this and making it workable.

The second point I wanted to speak to was your question about the amendment to the Food and Drugs Act. It is fair to say that the core of the problem with the current access to medicines regime has been the licensing process. The process about how you review the drugs for quality and safety and so on is secondary.

We should, if there are difficulties with something like the proposed subsection 38(1) that's in Bill C-393, look at that. If you feel it doesn't provide adequate protection for making sure that things are properly reviewed before they get to the countries, let's tweak it and let's make it work there, but let's not lose sight of the core objective here and use that as an excuse to not pass this.

The reality is if you talk to the generics—I think they'll tell you this next week—they're going to go through the Health Canada review process anyway, because that is the thing they are familiar with. So as you see in this proposed provision in paragraph 38(3)(a), all of the existing regulations that are made under part II of the Food and Drugs Act, section 30, which is the one that has all of the regulations about quality, safety, and efficacy, will be entirely applicable. Bill C-393 will not change that.

● (1255)

The Chair: Thank you, Mr. Elliott.

Now we'll go on to Mr. Kilby, please.

Dr. Don Kilby: I'll be very brief.

First of all, I want to thank you all for listening to us today.

I really do think, as Richard has said, that we have to take some risks to make this happen. The world has really taken risks already to get 5.2 million people onto therapy and has done things that nobody thought people from resource-limited settings were able to do. Every day people take risks. I think we have the capacity and the ability within our country to be really significant players and significant contributors to what is a global problem and to offer up a viable solution for procuring cheaper, affordable treatments for people affected by HIV and AIDS and other conditions.

The Chair: Thank you, Mr. Kilby and Mr. Elliott, for your testimony today. We greatly appreciate it.

For the members, before you go, please remember that Tuesday, because of the need for scheduling priority witnesses, our meeting will be from 8:30 until 1:00, with three separate groupings of witnesses. Also, please keep in mind that next Thursday will be clause-by-clause on this particular bill, and we'll need to have any amendments you're considering as soon as possible.

That said, the meeting is adjourned.

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