House of Commons
CANADA

Standing Committee on Industry, Science and Technology

INDU • NUMBER 055 • 1st SESSION • 39th PARLIAMENT

EVIDENCE

Monday, April 23, 2007

Chair

Mr. James Rajotte

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● (1530)

[*English*]

The Chair (Mr. James Rajotte (Edmonton—Leduc, CPC)): We will call the 55th meeting of the Standing Committee on Industry, Science and Technology to order. We have our third meeting today, pursuant to Standing Order 108(2), on our continuing study of Canada's access-to-medicines regime.

First of all, I want to apologize for the warm weather. I'm not exactly sure what happened, but I want to thank Mr. McTeague for bringing in the fresh air, as he usually does for this committee. He's one step closer to being competition commissioner of Canada.

We have our final meeting here. We have with us five representatives of either industry associations or companies.

First of all, from the Canadian Generic Pharmaceutical Association, we have Mr. Jim Keon, the president. Secondly, we have Mr. Jack Kay, the vice-chair, who is president and CEO of Apotex Incorporated. From Gilead Sciences Inc., we have Mr. Gregg Alton, senior vice-president and general counsel. From Canada's Research-Based Pharmaceutical Companies, first of all, we have the president, Mr. Russell Williams; secondly, we have Mr. Terry McCool, vice-president, corporate affairs, Eli Lilly Canada Inc.

Gentlemen, we have given ten minutes for each association. The Generic Pharmaceutical Association will have ten minutes, Gilead will have ten minutes, and Rx & D will have ten minutes.

We will start with Mr. Keon for a ten-minute opening statement.

[*Translation*]

Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association): Thank you, Mr. Chairman, committee members, for having me here today.

My name is Jim Keon and I'm the President of the Canadian Generic Pharmaceutical Association, the representative body for generic pharmaceutical companies in Canada.

With me is Jack Kay, the President of Apotex, the largest generic pharmaceutical company in Canada.

[*English*]

On January 24, 2007, CGPA provided its written submission to the government as part of the review of the Canadian access-to-medicines regime, and we've provided copies to the committee. If you have questions to ask in greater detail about the failures and challenges of the regime, I will be happy to answer those, and I hope that we have an opportunity to do so.

I want to clear up one misconception that may have emerged since the adoption of this legislation two years ago. We have seen and heard many times that not a single pill has been shipped under this legislation. While the statement is sadly true, it hides the fact of the real story about the donations of medicines made each and every year by Canada's generic drug makers.

Last year alone, Canadian generic pharmaceutical manufacturers donated nearly 100 million doses of medicines, with an approximate value of $20 million. These have been donated to Afghanistan, to South Asia in the aftermath of the tsunami, and elsewhere in Africa. Our companies have been there to donate first-line treatments for all of those medicines.

In fact, the Canadian generic pharmaceutical manufacturers were pleased to join Prime Minister Harper on February 16, in Mississauga, to highlight their substantial donations of medicines to Afghanistan.

But those are medicines that generic companies are currently manufacturing. Under the Canadian access-to-medicines regime, the products are under patent protection and are therefore by definition not being produced by generic companies.

I recall the initial optimism that greeted the announcement, back in 2003, that Canada would be the first country to implement the landmark decision of the WTO on the implementation of the Doha declaration on the agreement of trade-related aspects of intellectual property. But from that point on, the process and the outcome have become a disappointment.

More than two years ago, I appeared before this committee and stated that Canada's draft legislation to allow generic pharmaceutical companies to export patented medicines to developing countries was unlikely to meet the goal of getting affordable medicines to people who desperately need them. It became clear early in the process that the government intended to make too many concessions to brand-name drug-makers and that it would be virtually impossible for generic pharmaceutical manufacturers to use this scheme.

We stated at the time that the overall approach to the legislation should be a straightforward and faithful implementation of the WTO decision. It is clear now that even that might not be enough, as no eligible importing countries have applied to access medicines under the decision, despite the implementation legislation in five countries.

Therefore, we're calling on the Government of Canada to not only address the fundamental flaws in its own legislation but to also go to the WTO and use its experience in trying to implement the decision as the basis to call on countries to remedy the constraints of the WTO rules.

Without further ado, I'd like to turn the mike over to Jack Kay, who will tell you first-hand about the experience of Apotex in trying to work with this legislation.

● (1535)

Mr. Jack Kay (President and Chief Executive Officer, Apotex Inc.; Canadian Generic Pharmaceutical Association): Thank you for allowing Apotex the opportunity to present our real-life experience of trying to manoeuvre through CAMR, Canada's access-to-medicines regime legislation.

The Apotex Group is a leader in the research and development of generic innovative and biotechnology medicines in this country. We plan to spend over $2 billion over the next ten years on research and development. As I speak, we have over 600 medicines under development. With close to 5,000 employees, we plan to add another 350 people to expand our production capacity from one billion tablets and capsules per month to over 1.4 billion. Over 300 of the medicines we presently manufacture are exported to over 115 countries, all of this to meet our core Apotex value: to provide access to lifesaving, affordable medicines.

In Africa, hundreds of thousands of people die needlessly from HIV/AIDS every year because they do not have access to such medicines. The reason is simple: the multinational pharmaceutical industry does not like to reduce its prices, and it's better to sell to industrialized countries, where it can charge higher prices.

After listening to a speech by Stephen Lewis, we made a corporate commitment to do something about the problem. In 2002 we made an offer to the federal government of the day that we would produce five antiretrovirals at our cost, as long as the government got them to where they could be used in Africa. The government never even offered to look at our proposal. Part of the problem was that there was no mechanism to facilitate the process, and there was a lack of infrastructure for effective distribution. In the meantime, millions continue to die from HIV and AIDS.

Then in 2003 Bill C-9 was tabled, and hope was high that something was going to get done.

Here is a recap of the Apotex experience. We worked in consultation with Médecins Sans Frontières, who outlined the HIV/AIDS medicines that were in critical need and advised us that a combination drug of Lamivudine, Zidovudine, plus Nevirapine was needed. We started working on Apo-TriAvir, and a special R and D team was assigned to this project. They doubled their efforts, working weekends and overtime to complete the submission dossier. Many worked on their own because they wanted to do something important for HIV/AIDS patients in Africa. This drug could potentially save millions of lives, and Apotex was committed to providing Apo-TriAvir at cost.

At the same time, Health and Industry Canada defined an expedited approval route. Work on the fixed-dosage combination began in April 2005, and the submission dossier was finalized in December of that year. The dossier was approved by Health Canada in June 2006, and pre-qualification at the World Health Organization was achieved following the Canadian approval. This assured recipient countries of its efficacy and safety, authenticity and availability.

Apotex has invested over $2 million to date on the research and development of this drug.

Yet, having done ail of this to get this important HIV/AIDS medicine ready, the real problem for Apotex is the legislation, as the CAMR requirements are impossible to navigate. First, it's a voluntary license versus a compulsory license, requiring the recipient country to be identified up front, and the recipient country needs to initiate the request. The entire burden is left on the shoulders of the poor countries, who do not have the expertise or the resources. The legislation is designed for pharmaceutical companies doing business in the industrialized world, not Africa.

The effectiveness of the legislation is compromised by its lack of clarity. Maybe the objective of CAMR has to be clearly defined: quality medicines for critical diseases in a timely manner.

The current complex legislation tries to balance the interests of big pharma first. Why? We need to get our priorities right as Canadians and focus on those who are dying every day from AIDS in Africa.

● (1540)

This legislation perpetuates the human crisis, without getting anything done. Also, there is nothing stopping the multinational pharmaceutical industry from unilaterally making these drugs available at affordable prices, but they have not. All of their efforts have been focused on impeding the legislation.

In conclusion, our recommendation, having experienced the process, is that we need to move to a defined compulsory licence upon regulatory approval. This will speed up the process and limit legal costs, which can be substantial.

Thank you.

The Chair: Thank you very much, Mr. Kay.

We'll now go to Mr. Alton.

Mr. Gregg Alton (Senior Vice-President and General Counsel, Gilead Sciences Inc.): Thank you, Mr. Chairman, for the opportunity to address you and the committee today.

[*Translation*]

Thank you, Mr. Chairman, committee members, for the opportunity to discuss this topic with you today.

[*English*]

I am the senior vice-president and general counsel of Gilead. I'm also responsible for our access program, the program at Gilead making our products available in the least developed countries of the world. It's actually a program that I designed and that I run personally myself.

Currently through my department at Gilead we're providing antiretroviral therapy to approximately 50,000 patients in the least-developed world. That represents about 100 countries of least-developed status and about 50 countries in the middle-income markets. In addition to that, I serve on the board of a non-profit that operates 38 clinics treating over 50,000 patients in 15 countries throughout the world. So I do have personal, hands-on experience on the issues we're talking about.

First of all, I want to congratulate Canada on its decision to be the first country to take steps to implement the 2003 WTO decision on public health. We at Gilead share a common goal in removing barriers that limit access to essential medicines for people living in the developing world.

I'm going to share with you some of the experiences we have had in delivering access to essential medicines and our view of both the challenges that we at Gilead face in delivering medicine and some of the challenges that have been faced by CAMR—Canada's access-to-medicines regime—in this process. I want to make it clear that the comments that I make are the comments of Gilead and do not necessarily represent those of other members of our industry, although I do believe that our industry shares a common goal in this effort.

We're committed to meeting the needs of patients living with HIV throughout the world. We do this through scientific research and development programs, where we invent new medicines that give patients important new treatment options. In addition, we have developed a comprehensive access program that addresses the impact of poverty on the ability of those living in the world to afford our medicine.

The cornerstone of our access program is the responsible use of intellectual property. In nearly 100 least-developed countries—this includes all of Africa—our access program makes our HIV products available at our cost. There is not one penny of profit in our program.

We have also worked closely with middle-income countries, countries that have financial capabilities well above sub-Saharan Africa, and have pricing tiers offering substantial discounts to countries like Thailand, Mexico, and Brazil. We've worked very closely with these countries. We have a very close relationship. And they are very comfortable with our pricing strategies.

Last year we established partnerships with eleven Indian generic manufacturers to produce generic versions of our HIV drugs for distribution in the developing world, including all of Africa. There are 95 countries included in this program. The rationale is that these companies are the world leaders in delivering medicine to the developing world; they have proven this.

All of our agreements include a full technology transfer to enable our partners to quickly ramp up production of active pharmaceutical ingredients and tablets. Our partners are free to establish pricing for their products—we impose no restrictions on the pricing—and they pay us a 5% royalty on the price that they set.

The other thing I'd like to point out is that these licences do allow these partners to make fixed-dose combinations with any other products that are available to them.

For the current review process, we believe that CAMR should be realistically evaluated in the context of the role it can play to accomplish the objectives of the 2003 decision. Some critics are calling CAMR a failure because of its red tape and because of its complexities, and they believe that those have prevented its use.

I will offer two primary reasons why we believe CAMR has not been used—and these are some challenges that we are facing—and also offer some suggestions for how we believe it can be improved.

First, least-developed countries that do not have manufacturing capacity, countries that really are intended to be addressed by the WTO decision, are accessing a majority of their medicines today from India, where patents on pharmaceuticals have historically not existed, and through the access programs of the R and D companies like Gilead, where we've substantially lowered our costs. There has been no need for these countries to purchase from Canadian generic companies.

Critics have also pointed to the lack of drug access for patients in least-developed countries as evidence that CAMR should be simplified. I believe that this ignores the facts. Lack of drug access is and has been an issue despite the fact that low-cost generic versions have been available.

The problem is weak health care infrastructure. The problem is too few health care professionals and a lack of political will to make HIV care a priority in these countries. According to the latest World Health Report, for every 50,000 people in Canada, there were 500 nurses; in Uganda there were 31 nurses and in Ethiopia there were 11 nurses for every 50,000 people. How are we going to provide access to people if they don't have people to take care of them?

Until these barriers are addressed, actions by Canada, NGOs, the generic industry, and companies like Gilead are going to meet limited success in their programs.

CAMR is an important, comprehensive, and well-designed regime that balances the rights of patients in the developing world with the rights of the R and D industry. While CAMR has not been used to date, it could be an important vehicle for access if patents prevent least-developed countries from accessing affordable medicine.

● (1545)

This will be particularly important if, as India begins to enforce patents, generic or low-cost branded products are not available in these countries.

I will offer several observations based on our experience that you might want to consider during the review process.

At Gilead we have had tremendous difficulty working with developing world governments, NGOs, and international purchasing agencies in forecasting demand for product. A forecasting or quantity requirement in CAMR could disrupt the supply of essential medicines. It could make it more difficult to use the regime. The government should remove the forecasting requirement in CAMR and remain focused on ensuring that generics exported under CAMR go to the patients for whom they were intended.

We also don't believe that CAMR should prescribe a specific duration of licence. The appropriate duration of a licence will depend on multiple factors, including the issue that is driving the need for the licence, the nature of the disease, the cost and time required to establish and scale up manufacturing capability, and the annual volume of production required to recoup that investment. One thing I want to make clear is that Gilead conducts all of its manufacturing through contract manufacturing, so we understand what it means and the process of lining up new contract manufacturing. These are all issues that go into those decisions.

Finally, I'd like to say that we should not have a double standard for quality. Patients in the developing world should receive the same quality of products as those patients in the developed world. This is even more critical in the area of infectious disease, where substandard product can lead to resistance and treatment failure.

Once again, I would like to thank the Government of Canada and this distinguished committee for the opportunity to be part of this policy discussion.

Thank you.

The Chair: Thank you very much, Mr. Alton.

We will start with you, Mr. Williams.

[*Translation*]

Mr. Russell Williams (President, Canada's Research-Based Pharmaceutical Companies (Rx&D)): *Bonjour, monsieur le président*, members of the committee.

Canada's Research-Based Pharmaceutical Companies (Rx&D) applaud Canada for being one of the first countries to provide legislation that responds to the Third World's need for access to pharmaceuticals. Canada's Access to Medicines Regime was passed into law unanimously by Parliament in a spirit of compassion that reflects Canadian values. The innovative pharmaceutical community supports the generosity inherent in this legislation, which serves as a tool to respond to the need for medicines in the developing world. A global humanitarian crisis is unfolding and it must be addressed on an urgent basis.

[*English*]

First, let me say that l am aware that Canada's access-to-medicines regime has attracted critics who say the legislation is not working. To those critics, l would respectfully point out that this is young legislation. The Doha decision occurred in 2003 and the bill came into force in May 2005. In some ways, it has not been fully implemented. For example, an expert advisory committee under the legislation has not yet been established. It is therefore hard to say that the legislation has been fully tested.

l think this point is proven by the fact that the awareness of this legislation is very low. l met with about 25 ambassadors from African countries before Christmas and found that the majority of them were not aware of Canada's access-to-medicines regime. Health Minister Tony Clement recently echoed this view when he indicated that he had met with representatives from two African countries, neither of whom was aware of the legislation.

● (1550)

[*Translation*]

Before altering the legislation, it is our view that the government should give it an opportunity to be tested. Rather than rewriting Canada's Access to Medicines Regime, I would recommend, as a first step, that the government undertake a full-scale education program to inform stakeholders—especially those in developing countries—of the legislation and its mechanisms.

[*English*]

It is also important to view this legislation in a broader context. The pharmaceutical community believes that delivering medicines to patients in developing countries addresses only one part of a much larger health care challenge. Without transportation, clinics, clean water, or access to health care professionals, as just discussed, this legislation alone will not be very effective. The legislation should be therefore viewed as one element of a comprehensive approach to increasing access to life-saving drugs.

People working at the forefront of the AIDS crisis have spoken about the need for a coordinated plan to address the proliferation of HIV in Africa. Some humanitarian organizations have recommended that steps beyond access to medicines be taken. Canada has been urged to commit money to help cover the costs of HIV prevention programs. Developed countries have also been asked to forgive debt in return for investments in health care and to invest in the training of health care workers.

[*Translation*]

Rx&D agreed with this need for a comprehensive approach. We must look at legislated access to medicines along with an array of non-legislated measures. Together, they should be seen as an integrated approach to supporting Canada's health-care objectives in the Third World.

[*English*]

There is much more to do, as we all share responsibilities to find a solution to this cause. The innovative pharmaceutical community has for years—and it's one of the reasons why I joined the community—provided increased access to medicines in developing nations outside the legislation that is now being reviewed.

Over the last five years, the global pharmaceutical community has donated $5 billion in humanitarian aid, including medicines. This equates to positive health interventions for some 540 million people worldwide. You can find details on these efforts in the binder that we propose. I recommend that everybody take a look at them.

This money has been used to build health care infrastructure, as well as provide medicines and vaccines. We know that progress is being made. The World Health Organization recently reported that there has been a very significant increase in the number of people receiving AIDS treatment in sub-Saharan Africa—from 2% three years ago to 28%, 1.3 million people. Still, much work has to be done, and we have to commit a great deal of energy, but I think progress is being made.

The pharmaceutical community has also taken innovative approaches, such as preferential pricing at cost, below cost, or free in some cases. Voluntary licence agreements with foreign drug manufacturers have allowed us to reduce production costs and the end price for certain drugs. We have also invested in clinics and education to ensure medicinal products are properly administered. This is quite crucial.

On the home front, Canada's pharmaceutical community since 1990 has contributed almost $150 million in medicines and financial assistance to Health Partners International of Canada, where the Prime Minister was a month ago. This money has gone to hundreds of humanitarian efforts. This is an ongoing partnership that speeds the delivery of “in-date” drugs to people in need and avoids diversion to unintended recipients.

[*Translation*]

We applaud the government's decision in the last budget to provide incentives aimed at maximizing donations to organizations such as Health Partners International of Canada, because we know they ensure high quality medicines are delivered to people in need.

[*English*]

Clearly, there are many ways to provide affordable medicines to countries in need. Generics are one option, although people, including Industry Canada, say the price of generics in Canada is a barrier. But equally compelling is the fact that the innovative pharmaceutical community has provided preferential pricing on brand names to struggling nations.

Terry.

Mr. Terry McCool (Vice-President, Corporate Affairs, Eli Lilly Canada Inc.; Canada's Research-Based Pharmaceutical Companies (Rx&D)): This committee heard last week that the government should eliminate some of the safeguards, including the schedule 1 of lists. In our view, this is not a solution, as the schedule is one list and is not an impediment to the availability of patented products, as some people have suggested. In fact, 95% of the medicines on the World Health Organization's list of essential medicines are not protected by patents, and of the remaining few products on that list, those patents are not being enforced in developing countries. This means that no special legislation is needed to deliver these medicines to countries in need.

I would argue that the schedule 1 list facilitates the movement of drugs, as it creates a process for distributing drugs to developing nations. For this reason, I view the schedule 1 list as advantageous. Removing the list won't make this legislation any better.

I would also like to stress the importance of ensuring that other safeguards, particularly those focused on diversion, will remain in the legislation and be fully implemented. Any diversionary safeguards will ensure that patients in developing countries receive medications and that they are not diverted and sold illegally.

Corruption of the pharmaceutical supply chain is a serious problem in developing nations. It serves no purpose for Canada to be involved in this process, and it cannot, at a minimum, secure the drug supply and ensure that medicines sent from this country reach the people who rely on them.

I would also remind this committee of perhaps a less-known provision of the legislation, which provides for a 30-day period in which a generic drug company can negotiate with a patent-holding pharmaceutical company to provide a specific drug for export. It is my understanding that no generic has gone past this process and applied for a compulsory licence.

Safeguarding intellectual property also plays a role in access of pharmaceutical products. People tend to argue that access and intellectual property are mutually exclusive, but I disagree. I would argue that intellectual property creates access because it leads to new medicines. The fact is that intellectual property fosters research and innovation, and that leads to life-saving drugs and vaccines. It is therefore important that we do not put research at risk in this country.

Intellectual property regimes exist in developed countries because they create a climate for innovation to treat disease. They do not exist in many parts of the developing world. As such, Canada has a responsibility to create a regime that protects intellectual property and leads to greater access of prescription drugs among poor nations.

Our community believes it would be premature and counter-productive to alter Canada's access-to-medicine regime at this stage. The legislation has not been fully tested. Its efficacy cannot be fully known until awareness of the legislation increases and it is fully limited. Only then should alternatives be considered.

Changing the legislation now runs the risk of providing the wrong response to the challenges facing health care in the developing world. We encourage this committee and the Government of Canada to reach beyond the current legislation and consider a comprehensive approach to the delivery of medicines to people most in need.

Canada's access-to-medicine regime is only one piece in a continuum of efforts to address the health requirements of developing countries. By broadening its approach, Canada can continue to play a leadership role in the area of greater access to health care overseas.

Thank you. We look forward to your questions.

● (1555)

The Chair: Thank you, Mr. McCool.

We'll go now to questions from members. I'll just remind witnesses that members are limited to either five or six minutes in their time, so we would ask you to be brief in your responses and I'll ask members to be brief in their questions.

We'll start now with Mr. McTeague.

Hon. Dan McTeague (Pickering—Scarborough East, Lib.): Chair, thank you very much.

Mr. Byrne is not here today. He is back home with a bit of an ear infection as well, so he may be calling all of you very soon to help him.

Gentlemen, thank you for being here today, but you're here because there is one succinct, compelling message that was given to us last week by Stephen Lewis, the same individual who in my view is responsible for forcing the issue and turning the government towards this regime to begin with, to try to help deal with the undeniable tragedy that is unfolding. That's something I think you all agree with. It's just how we approach it that seems to the problem, the stumbling block.

I have a real concern when I hear numbers of 300,000 children in any part of the world dying as a result of our inability to get necessary drugs to them. At the same time, I think most Canadians recognize the importance of ensuring that diseases of opportunity are contained, so that they don't spread elsewhere throughout the world. We know about those circumstances. I come from a city that knows all too well the devastation of SARS.

I'm asking this to all of you here. I hear what Jack has had to say and, Terry, what you have had to say. We have an example of a drug that is ready-made, available to be there, and as in 2001, an NGO community that tells me that where Canada can have an impact in 5% or 10% of the places that are currently affected, they can in fact provide the regime, can provide the opportunity for and the delivery of proper medicines. So I don't think that's at issue here. Certainly, in terms of impact even 1% would be better, if it even saves one life. I think we all agree with that.

The condemnation of this regime, of CAMR, comes as a result of its inability to actually help. There are examples of situations where, I'm sure, you provided medicines, and the Prime Minister has been there to launch the HPIC initiative. That's great.

I'm wondering, going forward, how credible it is for us to sit at this table and conjecture about what the problems are, when in fact today thousands of children are going to die in that part of the world very much as a result of our rhetoric here. I know you all have your vested interests; you have interests in doing what you're doing. I'm wondering why, in your view, we cannot go from a voluntary system to a compulsory system, allowing the country to make that decision, working with our good and well-intentioned NGOs?

I'll leave that open to you, Mr. Kay, and to you, Mr. McCool, if you don't mind, or Mr. Russell.

● (1600)

Mr. Jack Kay: That's exactly what we've been advocating, to remove the process by which we have to go through a voluntary licence. All that does is tie us up. Then, if we're refused a voluntary licence—and we have been refused—I then have to engage lawyers to go through the process of applying for a compulsory licence. Remember that I am going to tie up resources from within my company, people who are doing other things, researching other products on which we make a profit.

We are prepared to provide these life-saving products at our cost, but we cannot tie up our resources to fight a battle in order to get the licence. When the licence regime was established, it was flawed. We told the government of the day at the time that no company would take advantage of it, the way it is currently structured.

MSF came to us and told us they had a country that wants the drugs. They want to buy made-in-Canada products because of the quality. We told them we could produce the drugs and asked them to help us get a licence. We're still trying to get a licence.

The Chair: Mr. McCool.

Mr. Terry McCool: Certainly. I'd be happy to comment. The voluntary licence is a very simple process. It's 30 days. That's no more than notification to a brand-name company; it's not a delay. It's a notification that you have an order, what the quantity is, and where the order is going. For the brand-name company, which often has to go to its global headquarters to determine what patents are being... where the compulsory licence is being issued, 30 days is not a very long period of time to do that.

If the decision isn't made in 30 days, you don't need a lawyer to go to the Commissioner of Patents. The Commissioner of Patents is instructed to approve these things very quickly. It's not going to take you time and effort to do that.

To our knowledge, in spite of what Jack claims, no one has gone that far to get a compulsory licence. Until somebody actually does it, I can't see that being an impediment.

Mr. Jack Kay: The impediment in this case was the fact that the country that wanted the product did not want to be identified.

Hon. Dan McTeague: So there's an issue of identification.

Let me turn a little bit to the other issue that has been raised by the committee and by many of the people who have come before us. There is concern now about the possibility that the diseases are taking on new characteristics and morphing into different, more virulent types of disease, and that those are giving way to the possibility of other diseases of opportunity. Five years ago, we had a certain regime of drugs that were available. We now have a second generation.

Mr. McCool, I'm wondering how much of those second-generation drugs your industry has provided, at their cost, to various regions to alleviate and to bring down the number of cases of individuals afflicted.

Mr. Terry McCool: I think there has been quite a bit provided. If you look at some of the background that was presented, there are aid programs in many countries in Africa. The newer drugs are being reduced in price and are available in some of those countries.

One of the issues you brought up is if the drugs aren't used properly.... These are prescription drugs. You can't just ship them and give them out. You have to have some supervision by a health professional. There's such a shortage of health professionals that I think there's an issue with drugs being able to get to those countries.

Hon. Dan McTeague: Mr. McCool, when I had Médecins Sans Frontières and Oxfam do a joint letter—the letter is still on my website—to the Prime Minister, they said they could in fact deliver proper medications with the assistance of physicians, or whoever.

I'm wondering how much success brand-name companies in this country have had in working with those same NGOs, who are highly critical of the role of the brand names, as we saw here last week. I'm not pulling any punches here. This is a reflection of the fact that we've heard from two.... We've had a chance to hear from the representative from Gilead.

Have you in fact been working with NGOs? Who are those NGOs, and how successful have you been?

● (1605)

Mr. Gregg Alton: I could answer that question.

Our products are second-line therapy. They're considered second-line therapy in the developing world. As mentioned, we're providing product to about 50,000 patients in this area. I think we work well with MSF, with UNICEF, and a variety of other organizations throughout the world.

We have a fixed dose combination: a full regimen—one pill once a day—that we've co-developed with Merck. We're making that available through our access program in all these countries, and this is available from us today.

The Chair: Thank you.

Sorry, we're over time. We'll have to go to Madame Brunelle.

[*Translation*]

Ms. Paule Brunelle (Trois-Rivières, BQ): Thank you, sirs. We're glad you could join us today.

I'm trying to understand why the legislation hasn't worked and why no pharmaceuticals have actually been delivered. The Canadian HIV/AIDS Legal Network told the committee that a number of developing countries were not in a position to buy patented medicines, besides which they lacked the industrial capacity to manufacture their own generic pharmaceuticals. They must depend on countries that export pharmaceuticals. Hence the need, of course, for this legislation. It's clear that a need for such products exists.

Moreover, during the course of two meetings, many reasons were given as to why the legislation has failed. Mention was made of the lack of information about the regime— you pointed that out again today. We heard that there wasn't even website up and running. We heard comments such as the complex nature of the regime, the lack of support measures, whether in terms of transportation or clinics. We were even told that at times, some areas are without water. Therefore, the process of sending pharmaceuticals has been hampered by major, fundamental problems. We heard how drug shipments were being diverted. We've seen news reports on this problem and it's easy to understand why it is that in war-torn countries, where even food shipments are diverted, pharmaceuticals are also valuable commodities. We also heard that in some cases, the list of pharmaceuticals in the schedule was overly restrictive. Many other reasons were also cited.

My question for Rx&D officials is this: what efforts are your companies making to supply affordably priced pharmaceuticals? It's clear a need exists. I would also like to ask all of the witnesses to explain why the regime isn't working and what steps they have taken to come to an agreement as to how to make this legislation work.

Mr. Russell Williams: With your permission, I'll go first. Thank you for asking such detailed questions. I'm not convinced that the process is not working. I don't think that has been proven yet. One of the reasons why the program hasn't been used thus far is the price of generic products in Canada. You can add that to your list of reasons. However, I'd like to explain that the act isn't quite that complex. There are certain requirements: where does the request originate, what quantity of product is being sought, who will be using them and for how long. It doesn't seem all that complicated to me.

Unfortunately, to date, generic companies haven't proceeded to step two, that is to test the system. If we want assurances that new HIV drugs are effective, we need to do some research. We're trying to strike a balance between protecting intellectual property and providing access to drugs. One does not preclude the other. First we need to let countries know that we have legislation on the books. That's why I visited 25 embassies to explain the act. We can start by letting the public know that this act does exist. In addition, we have documented proof that our R&D companies have partnered a great deal with other countries and with NGOs, the non-governmental organizations. We operate in the field successful programs providing access to drugs, clinics, and health, education and professional training systems. In my view, we need to take a comprehensive approach. We can continue to support the act while advocating that Canada take a comprehensive approach to this issue.

Summing up, I hope that we will be successful and that very soon, we will have a product that passes the test from every angle, a product that will allow for the system to be used while other countries continue to develop access programs.

● (1610)

Mr. Jim Keon: Clearly, it is the generic companies, and not the large multinationals, that need this act. The legislation refers to patented medicines. The changes that we have proposed need to be made in order to make the act more effective. The existing act is overly complex and negotiations must be conducted with patented drug companies. In the case of Apotex, three companies held a patent on this product. The license is valid for only one country, but often, companies want to export the product to several different countries. A company needs to be have a license that is valid for a certain period of time. Right now, under the act, a license is valid for only two years. In many ways, the act's provisions are restrictive and, as we mentioned two or three years ago, it's impossible for a generic drug company to work with the legislation. Therefore, it's important that changes be made. This act is important to all countries, and especially to developing countries.

Ms. Paule Brunelle: So then, in your opinion, Mr. Keon, a number of amendments are warranted. Do you consider the list of pharmaceutical products appearing in the schedule of the act to be another hindrance? Should this list be modified?

Mr. Jim Keon: We would rather see the list abolished, but in actual fact, that's not what is most important. However, the list is an example of a superfluous provision. Anytime we want to add new products to the list, it requires a great deal of work on the part of government officials, companies and just about everyone. In the past three years, I believe we've added two new products to the list and each time, the process has taken six or seven months to complete. In my view, the preferred option would be to do away with the list, but that isn't our top priority.

[*English*]

The Chair: Merci.

We'll go now to Mr. Carrie.

Mr. Colin Carrie (Oshawa, CPC): Thank you very much, Mr. Chair.

Thank you all for coming here today. I have so many questions for you, so I'm going to try to get right to it.

You mentioned the government's recent budget, and how the government offered tax incentives to generic and brand-name pharmaceuticals that donate medicines overseas. Can you tell us what sort of impact this change may have overall in terms of Canada's access-to-medicines regime, and particularly for CAMR and your company? Is it going to have any effect there?

Mr. Gregg Alton: I'd be glad to answer that question.

I think that philanthropy and donations of drugs and other assistance from the R and D industry or the generic industry is important and can meet some important needs in the countries. However, I do not believe that philanthropy is going to solve the problems of continents like Africa. I think the change is going to have to come from within the countries. I think there's going to be only so much the western world can do in terms of donations to those types of programs. I think it's a good step forward and it will have a positive impact, but it's not going to fundamentally change the situation in Africa, which is developing the health care infrastructure and the ability to pay for medicines, and the poverty and the impact that's having.

Mr. Russell Williams: It is an excellent step forward. We're trying to find out how to use it best. As you know, it's just been announced, so it hasn't been fully implemented. I think it speaks to the question that this has to be a comprehensive approach. Whether it's this law, whether it's philanthropy, other training programs, infrastructures, roads, education, if we're going to attack this—and this is what the AIDS activists have told me—we have to approach it globally. I think it's one more tool in our tool chest that we should exercise. We should be proud of it. We should use it, but there are many more things we could be doing.

● (1615)

Mr. Jim Keon: To respond quickly, the tax changes I think are great. I think for donations, philanthropy, it will increase the incentives for companies to do that. I would agree with Mr. Williams that we need a comprehensive approach. That's why we're saying changes to this legislation are necessary, because right now we're talking about patent medicines; we can't make those, even with tax advantages, unless this legislation works properly. This legislation had a two-year review—that's now. If we don't make changes now, no more review is scheduled, and I'm not sure when we'd ever make those changes.

Mr. Colin Carrie: I think we're all trying to figure out the best way to deliver what needs to be delivered to these countries and to try to figure out if the legislation is broken, or if there's something else that needs to be done. I'm quite interested in something that Mr. Alton said, that you supply products to countries that require it, but you're sourcing some of these drugs out of countries such as India. Why aren't you using Canadian companies? Is it a price thing? Did I get that right?

Mr. Gregg Alton: Let me explain this. We have a couple of different products. Our branded product is currently manufactured in the Caribbean and also here in Canada, so there is a Canadian drug that's actually meeting the needs of patients in Africa through Gilead's access program. The Indian generics would be true generic products that would then be in these 95 countries. Our branded products would be there as well. They would all be competing within the marketplace.

The rationale's not so much focused on price. We believe the prices of our products are as low as they can go. Believe me, if we could lower our manufacturing costs, we would, because that's good for our business, but we've really worked very hard to get it about as low as we can. In fact, most of that work's now being done in our facility in Edmonton on manufacturing efficiencies.

The reason we want to work with the Indian companies is that they have a very good ability to get drugs to patients in the countries, based not just on price, but also on their understanding of the health care systems and their understanding of who the people are and how to work within a very difficult environment; we, as a western company, are not well equipped to do that.

When you talk about CAMR and the fact that it hasn't been used to date, I think part of the reason is not that it's a failure, but that a lot of the programs in place are actually doing the types of things that Gilead is doing.

We're having a lot of talk in this room about the desire for CAMR to be used, or that it's a failure because nothing's been used, but the goal of access, the goal of CAMR, and the goal of the flexibilities built into TRIPS should really not be to break patents or to override patents, but to provide access. That should be the overall goal. The fact that it hasn't been used may actually be showing that some of the things actually happening out there are working, or are at least working as well as they can within a very difficult environment.

Mr. Colin Carrie: One of my concerns was just brought up; I believe Mr. Keon mentioned it.

You're looking at quality of a product, too. Countries like India don't have IP protection. With the way it appears to be going, I was just curious about whether this is going to force companies like the generic Canadians to set up shop in India in order to compete with other countries or with other companies that are already there. Are we saying we're going to be moving all our manufacturing offshore now? Is that a reasonable thing for me to...?

Mr. Gregg Alton: No, I do not think that manufacturing will move offshore from Canada. Gilead does a substantial amount of manufacturing in Canada because it's a great place to do business for manufacturing. We have high-quality manufacturing, great capabilities, and a very educated, skilled workforce here, so I think this will always be a good place to manufacture.

In India they've just been doing this for a long time. They haven't had patents, historically. They are now actually adopting the TRIPS requirement to enforce intellectual property, so I think it remains to be seen what impact that will have on the developing world for access to medicines.

As I mentioned in my testimony, I think that's an important role CAMR could play. If the availability of low-cost generics is cut off from India, that could be a good place for CAMR to provide a safeguard to ensure that patients still receive access to those medicines.

India has similar legislation in place as well, so my guess is that a lot of those countries in the developing world will go to India, even under a compulsory licence regime.

● (1620)

Mr. Colin Carrie: This question is for the Canadian Generic Pharmaceutical Association. If all the red tape disappeared from the Canadian legislation, would you be able to provide medications from Canada to the less developed countries, and if you could, how?

Mr. Jack Kay: We have been in discussion with MSF. MSF have come to Apotex and asked us to produce a quantity of this triple combination therapy, which we have produced. We can supply it. The price at which we're prepared to supply it is competitive with products that would come out of India. The only reason we have not supplied it to MSF, who have assured us they will get the products to the patients who need it to save lives, is we cannot stickhandle our way through the current legislation.

The Chair: Go ahead, Mr. Williams; please be brief.

Mr. Russell Williams: In terms of the current legislation, we're looking at four basic bits of information: which country's asking for it, who's using it, the quantity—very straightforward questions—and if that's a 30-day process. If that doesn't work, the generics could move forward. Our role is very small in this. The generics could move forward and seek a compulsory licence, as Mr. McCool said. They have not done that yet, so to say that the law doesn't work when it hasn't even been used I think is rather premature. That's why we're also so active in other areas.

The Chair: Thank you.

Mr. Masse is next.

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

Thank you, gentlemen, for coming here today to present on a very important issue. It's the reputation of this country, I believe, on the line here.

I'll start with Mr. Williams and Mr. McCool.

You repeatedly said you need more time for this legislation. The fact of the matter is that this legislation came about after 550 days of review. It took that long, over a year and a half, to actually get a piece of legislation, which since that time hasn't produced anything.

Right now, if it's still, in your view, premature, how much more time is needed and what needs to change, specifically, for this legislation to be successful? I'd like to know, because the body count is rising. I think we're actually participating in a wilful genocide of people, because we actually have systems in place and we use excuse after excuse after excuse.

What is the timeframe, would you say, before there has to be a full-blown investigation and people held to account if we still don't get a pill to someone else? Is it one year, two years, three years, four years? What is it?

Mr. Russell Williams: First and foremost, I think we should be doing everything in our power to work on this important issue, I agree with you. I've tried to list some of the things we were doing long before the bill turned to debate. So I don't think there's any argument there.

I would love to see the bill tested. If we're talking about a product that potentially could do the kinds of things you're talking about, let's take it through the process. We're talking 30 days. Then let's take it to compulsory licensing, and let's move forward in that process, as Mr. McCool said.

So let's move forward and let's test the bill before we say it's not working.

Mr. Terry McCool: I would just add that you need a country to order the product. That's what you need. From everything we've seen to date, either a country is not willing to be identified or it's not willing to participate.

Mr. Jack Kay: So if a country doesn't want to be identified, let them die.

The Chair: One at a time, please.

Mr. Terry McCool: I just want to say, you had 146 countries sign the declaration at the WTO. They all agreed to that process. It's very simple. All they have to do is say they need a supply, and then they can come to the Canadian generics to get it if they want. Right now, their needs are being satisfied by either the Indian generics or the brand-name industry through their philanthropy or selling drugs at no cost.

Mr. Brian Masse: Have any of your organizations approached a developing country and said, “Let's work on doing this specific legislation”? Tell me how many times you've approached different countries, how far you've brought that case along, and where is it in terms of.... Specifically, what resources have you spent on going to different countries on that list? Because I'm a bit concerned about saying, “Developing countries, it's your fault. It's your fault that you can't figure out how to actually make this bill over in Canada work.” I don't accept that as a position for this country.

So I'd like to know when you've actually gone to a country, what that country is, what you've done work on, and when you're going to actually bring forth a case where you'll actually let a generic produce a drug at a cheaper cost.

Mr. Terry McCool: We're not in the business of HIV/AIDS drugs, but we're in the business of multi-drug-resistant tuberculosis, which is often fatal to people who have AIDS. We have negotiated with the South African government. We have negotiated with the Indian government. We have negotiated with the Chinese government. We've also negotiated with Russia.

What we've done is we've created, through technology transfer, the ability of all four of those countries to produce two very old compounds that have been off patent for years, but nobody wanted to invest in developing them. We've provided the technology, the tech transfer, the training, and $150 million in funding to increase the supply of these drugs in the third world. That's what we've done.

● (1625)

Mr. Brian Masse: Why aren't we using this legislation then?

Mr. Terry McCool: There are no patents on those drugs. We don't have to go through the Canadian legislation.

Mr. Brian Masse: This is the whole point, though. This system was set up so that actually could change. That's the whole point of this legislation, that there was actually supposed to be a place for developing countries and NGOs to get together to actually access those medicines. But I asked specifically, in terms of using this particular piece of legislation, what you have done to approach another country to say let's use this bill and make it work.

Mr. Russell Williams: Let me just quickly, and then Mr. Alton can respond.

Mr. Brian Masse: Then we'll turn it over to the other panel.

Mr. Russell Williams: Personally, I went and met with a group of 25 African ambassadors to talk about this legislation. I wasn't blaming anybody, please, and I don't think you really were meaning to say that I was.

Mr. Brian Masse: Your position is it's their fault if they're not using—

Mr. Russell Williams: No, my position is not that it's their fault. My position is they didn't know about it. They weren't informed about it.

So to your question, one of the things we did is we went out and started talking to them. We have now been communicating to them. It's not up to us to tell all the details of it, but we did our best. We made sure of all the links to get interest, so this actually would be used. It seems to me that's one thing that we could do. We could do other things, and I'm recommending that we should get much more engaged to make sure that everybody knows about the very steps of the law. It's not that complicated. Frankly, when we are trying to save lives, it seems a very basic question of saying that if we're going to move product to this country, we should know which country it's going to. I think that's a pretty legitimate, basic kind of question that we should be asking.

If we can get those four questions answered, let's start moving on that. We've been trying to encourage that. I agree with you. We did our best, as an association, to start informing those countries, and we'll continue to do that.

The Chair: I have Mr. Kay, and then I have Mr. Alton.

Mr. Jack Kay: I have no comment. It's just too frustrating. They're saying that they're making it easy, go, you have to answer these four questions. But if in fact an organization with the reputation of MSF comes to us and says "We have this country that wants to buy the product, and the price you're prepared to buy at is competitive with the Indian companies, but the difficulty is that the country does not want to identify that it needs a handout from Canada", it's just frustrating.

Mr. Jim Keon: The other reason why countries don't want to self-identify is they become a lightning rod for political attention and negative attention from the brand-name pharmaceutical industry.

Recently in Thailand, with a drug called Aluvia, an anti-AIDS medicine, the Thai government said it was going to issue a compulsory licence to import the product from India. Abbott, the owner of that patented product, threatened to pull seven other products off the market and put tremendous pressure on that country. Eventually, because of pressure from a lot of the NGOs and political pressure, Abbott backed off and is now making the product available at lower prices. However, without an effective functioning compulsory licensing system and without the threat of generic competition and lower prices, that would never happen.

Countries don't want to self-identify because right now they don't see an effective regime, and it's very difficult for them.

The Chair: Thank you.

Mr. Alton.

Mr. Gregg Alton: Thank you.

To answer your question, honestly, we've never gone to a developing world country and said, "Why don't you go use CAMR?" But I would say every day of every week we have Gilead people who are in the developing world, whether this be Africa, Latin America, or Southeast Asia, working with ministries of health, talking about how we can meet the needs of their AIDS programs and how we can work to get our products to their patients. So I can specifically say we've met with Thailand in the last couple of weeks. We have people in South Africa today. I'll be going to India next week, meeting with the government there. We have in all cases been able to work out arrangements where they can access our drugs and get the drugs to the patients they feel need to have our drugs, second-line therapies at affordable prices.

Specific to Thailand, we've had a very good relationship with the new government in Thailand. They are very comfortable with Gilead. We've met with them. We've met with their GPO, a generic company there, and their decision was that they're happy accessing the drug from us.

In my mind, if—

The Chair: I'm sorry, we're way over time, Mr. Alton. I'm sorry about that. We have to continue. Mr. Masse will have another turn shortly.

Mr. Brison.

Hon. Scott Brison (Kings—Hants, Lib.): Thank you, Mr. Chairman. Thanks to all of you.

We have what is a multinational challenge in Africa in terms of addressing the crisis and spanning both a range of national governments and the NGO community. Canada, Denmark, Sweden, and I believe France as well have legislation that is similar, but they have had failures in terms of delivery. There have been some success stories and the Clinton Foundation is in fact distributing HIV drugs successfully.

Have your companies approached the Clinton Foundation, for instance, to work with them, an NGO that is actually having some success in making this happen?

● (1630)

Mr. Gregg Alton: The answer is yes, we're in constant dialogue with the Clinton Foundation. They recently put out an RFP for purchase of our product and a variety of other products, and we are putting in a bid on that as well as the Indian companies we work with.

Hon. Scott Brison: So there is some success in terms of that, but from the generics and also the—

Mr. Jim Keon: We've had several discussions with the Clinton Foundation and, as Jack has said, Doctors Without Borders, identifying the patented products that might be of interest to them.

With respect to the non-patented products, as Jack mentioned earlier, he's now shipping to over 100 countries products that are off patent, but for the patented products, yes, we've had discussions with them.

I can tell you right now that in many ways what we need is some success with this legislation so that people can see that it actually works. We haven't had that yet, so they've lost a little bit of interest in the Canadian legislation.

Hon. Scott Brison: Mr. Keon, you mentioned the off-patent products. As we know, tuberculosis and malaria remain massive challenges in Africa. The drugs to treat those have by and large been off patent for years.

Mr. Kay, does your company have a program to ship drugs to Africa for TB and malaria?

Mr. Jack Kay: In our current product line, we do not have any agents for the treatment of tuberculosis or malaria. We've never developed generic equivalents because there wasn't a demand in our major market, which is Canada.

Mr. Jim Keon: I think where you find the generic companies developing those products are mainly in the developing world, where they have more access, unfortunately, to the illnesses and more ability to carry out the clinical trials, etc.

It's simply not that practical here to carry out clinical trials on a number of those products.

Hon. Scott Brison: But you developed a drug specifically around MSF's specifications for combating HIV in Africa.

Mr. Jack Kay: That is correct. We did.

Hon. Scott Brison: The Bush administration recently announced a multi-billion-dollar initiative on HIV in Africa. Given that western governments need to cooperate more closely to address this, and given that some of you represent multinational corporations, are your affiliates in the U.S.—or your parents, in some cases—working with governments in other countries to address this, to try to make this work?

Mr. Terry McCool: We are working with all of the major funding bodies that are involved with the procurement of drugs. Some of that work on our side, as I mentioned earlier, is through technology transfer. There are a number of AIDS companies that have transferred technology to generic drugs in both India and in Africa.

Hon. Scott Brison: The challenge we have is that we're seized with trying to figure out what the real problem is. Some of you are saying that the legislation isn't the real problem. Some of you are saying the governments of potential recipient countries are part of the problem. I don't buy any of this completely, but I don't reject any of it completely.

It's really going to take goodwill in terms of addressing this. When was the last time you guys—and I'm talking about the generics and the R-and-D-based pharmaceutical industries—actually met, outside of coming to a parliamentary committee, to talk about how you are going to make this work?

Hon. Dan McTeague: The last time the Liberals and Conservatives did the same.

Hon. Scott Brison: But we're supposed to be partisan.

No, but have you had meetings, outside of coming to a parliamentary committee, on how you're going to take an existing piece of legislation and make this work?

Mr. Jim Keon: You had two questions. The first was about dealing with the Bush administration and others. Again, this legislation has nothing to do with generic companies providing medicines abroad that are not covered by patent. This legislation has nothing to do with brand-name companies providing their products, whether it's philanthropically or for sale, abroad. They can do that now.

This legislation is intended to allow generic companies to access patented medicines. I think we should stay focused on that. It's all very good that we have donation programs and the brands have donation programs. It has nothing to do with this legislation.

And as far as talking to the brand-name companies is concerned, I would say that their intention here is to ensure that the legislation protects the interests of brand-name companies, and it's not to ensure that generic companies are able to make copies of their patented products and ship them abroad.

So we have not had discussions with them.

● (1635)

The Chair: Thank you.

Let's let Mr. Williams respond quickly.

Mr. Russell Williams: In my old political life I think we never inferred what intention was from other sides, so I would ask Jim to do the same.

I am very interested in finding ways to make sure that this law is fully tested. I don't accept that we haven't gone through the process and we throw up our arms and say let's go back to rewriting it. I don't believe that's the right solution.

So I do believe that we have to build on all the things that we're doing in terms of access and partnerships with various funds. I believe we should be partnering with health care networks. But I also believe that we should fully test this bill all the way through before we rewrite it.

The Chair: Thank you.

We'll go to Mr. Shipley.

Mr. Bev Shipley (Lambton—Kent—Middlesex, CPC): Thank you very much.

It is really interesting to have this type of a panel in front of us and I really appreciate it.

We just went through a manufacturing study where one of the key issues was the protection of intellectual property. I don't think there is anyone around this table who would not want to make sure we protect intellectual property.

What we're trying to do is make sure that we protect it, I think, and yet put some vehicle in place so that the medicines that are required in countries can get to them in countries where sometimes the legislation to protect that is not to the same standard that we have, the same concern. That's more of a statement than a question, because I'm sure everyone would agree with that.

I want to follow up with Mr. Kay. The 30-day process for a voluntary licence, have you finished that?

Mr. Jack Kay: We did apply for voluntary licences. It was complicated because of this triple-combination product. There are four different companies that have patents on the components. So we attempted to get a voluntary licence and we got bogged down.

Mr. Bev Shipley: You've never gone through that 30-day process to get to the compulsory licence, to make application.

Mr. Jack Kay: That is correct.

Mr. Bev Shipley: You haven't gone through the process, but you're saying it takes more than 30 days.

Mr. Jack Kay: It really comes down to the fact that Apotex is in the business of making money for its shareholders. We have decided to do this because the government passed the legislation. We tried to work through the legislation because MSF came to us with a bona fide order for the product.

I am not going to tie up my resources, our legal departments, in order to go through the process of trying to get a compulsory licence, because it's just far too complicated. The Government of Canada should facilitate this, because it's the right thing for us to do as Canadians.

Mr. Bev Shipley: I think five companies were producing the product you were talking about. When I look at them—and I can show you this if you want that—Apotex has the highest pricing of the five. In terms of the generic medicines, is that still...even though there's a variation? I think you said you were still price-competitive.

Mr. Jack Kay: The product you have here that we spent $2 million developing is sold in Canada by the patent holders—when you combine the different components—at around $4.50 per tablet. We have offered this to MSF at our cost, which is 39¢. So I'm not sure what list you have in front of you.

● (1640)

Mr. Bev Shipley: It's likely from other generics in other countries.

Mr. Jack Kay: I don't know what you're referring to.

Mr. Bev Shipley: Okay. I can show you that.

One of the things you mentioned...it was kind of weird. We seem to focus a lot on AIDS, but when I was looking at the reports, malaria and other diseases are killing huge numbers of people, and the same issues came up.

Mr. Kay, you said something to the effect that you don't produce a product for malaria. Your major market is in Canada, therefore there's no demand for it in Canada because we don't have malaria. Yet malaria is a huge killer in these underdeveloped countries. We have issues in Canada with HIV/AIDS so we are producing products for that, as you've shown here, but because malaria isn't an issue in Canada we don't produce the product. How do we get around that?

Mr. Jack Kay: I think those products are available at competitive prices out of the country, in places such as India, which has a very progressive and sophisticated generic industry.

Mr. Bev Shipley: So I think your answer is that we can get those from other countries.

Some of the NGOs that came to us the other day said we need to be concerned because India and some of these other countries will not be able to continue to produce the quantity of pills we need. As they progress, though, they will start to bring in patents and get stricter. So how are we going to be able to manufacture those pills if we're not able to be competitive?

The Chair: We'll make that the last question.

Mr. Keon.

Mr. Jim Keon: I think you're absolutely right, Mr. Shipley. India has been called the pharmacy for the poor world because it didn't have patents. Starting in 2005, it now does have patents. If in the future we find, as Jack said, that India and Indian companies are not able to produce these products at low prices and make them available, the Canadian legislation will become very important. It's quite possible that Canadian companies will be interested in making these products and some of the NGOs will be interested in buying them. We haven't needed to do that, but in the future we might.

The Chair: Thank you.

Monsieur Crête.

[*Translation*]

Mr. Paul Crête (Montmagny—L'Islet—Kamouraska—Rivière-du-Loup, BQ): Thank you, Mr. Chairman.

A few years ago, when the act was passed, I thought it would be the one piece of legislation of which I would be most proud upon leaving this Parliament in which I have served for the past 14 years. The reality is that it is the legislation of which I am the most ashamed.

Do you share my sentiments?

Mr. Jim Keon: Yes. We are very disappointed.

[*English*]

The Chair: Go ahead, Mr. Williams.

[*Translation*]

Mr. Russell Williams: I'm not disappointed about the principles of the act. I think we can be proud of them. I too was proud of this piece of legislation. Our industry has steadfastly supported this act's fundamental principles. Despite differences of opinion as to how the act should be applied, I hope that we don't lose sight of the act's objective, which is to come up with a system to help people who are sick. The legislation is not as effective as it was expected to be and unfortunately, it has not been used to its full potential.

Mr. Paul Crête: Would you be willing to take part in a pilot project in five countries where the government would commit to setting up an advisory committee to inform people about the act and to ensure that it is working well? One project would be carried out in each of the five countries. The impression we have today is that both sides are trying to shift the burden of drug problems onto the backs of the world's poorest. I find that very hard to accept.

Would you be willing to adopt a positive attitude and to work with the government to set up and test five projects? In a year or two, we could determine whether or not these projects have been successful and what legislative changes need to be made. Right now, it's as if we're commenting on a bicycle that has never worked. We say that it needs a different chain, when we've never really tried it out. We've even managed to scrape our knees a little trying to get off the bike. The fact is, we're not dealing with scraped knees, but with people's very survival. Would you be prepared to commit to such an initiative?

● (1645)

Mr. Russell Williams: The overriding principle here is...

Mr. Paul Crête: We could carry out five projects in five of the world's poorest countries over a two-year period, for example.

Mr. Russell Williams: We are involved on several levels. The Rx&D firms will continue to work in partnership on all projects designed to provide assistance to Third World countries. We are proud of this accomplishment and of our companies. Our role under the act is limited to a 30-day period, but we will do our job. We'll do everything we can to ensure the act works. Failing this, I hope the next phase will be put to the test. I will be the first one happy to see Canada find another way of supplying drugs to the Third World.

Mr. Paul Crête: Either Mr. Kay or Mr. Keon.

Mr. Jim Keon: As Mr. Kay mentioned, Apotex has already poured $2 million into a pilot project. If this project works well, I'm confident other companies will be ready to move forward with the legislation.

Mr. Russell Williams: According to the act, our responsibility ceases after 30 days, but our work in the Third World continues. We will meet our other obligations. We will never throw in the towel. We have already forged several partnerships which we intend to maintain.

Mr. Paul Crête: I'm sorry, but no one has done their job, and that includes us. You stated in your submissions that the government had failed to put in place the necessary infrastructure. Companies have not managed to test one fully. I'm telling you to test three. That's all I wish to say on the subject.

If I understood you correctly, Mr. Alton, your pharmaceutical product will cost an average of $240 in disadvantaged countries where the gross per capita income is $825. And we're not even talking about the world's poorest nations. That would be like someone paying $12,000 for drugs in Canada, on an annual income of $40,000. Can anyone in Africa afford this kind of drug?

[*English*]

Mr. Gregg Alton: No, no. Affordability, even at our cost, which is as low as we can drive the cost down, is still great.

I think a question came up about PEPFAR as another source of funding. More money is needed to purchase products, even if they're generics, even if they're coming through our access program in Africa. Almost half the product being purchased in Africa is being supported by President Bush's PEPFAR initiative, the initiative of the United States; the vast majority of the rest of it is coming from the global fund. These countries can't even afford the cheapest products.

[*Translation*]

Mr. Paul Crête: May I ask one last question?

[*English*]

The Chair: You're over time. *Brièvement, s'il vous plaît*.

[*Translation*]

Mr. Paul Crête: Thank you very much.

[*English*]

The Chair: Everybody is over time today.

[*Translation*]

Mr. Paul Crête: For the sake of Canada's image, do you not think this cause merits as much financial attention as the war in Afghanistan?

[*English*]

Mr. Gregg Alton: I think it's a question for Canada, as far as the image is concerned. I do believe that substantially more resources need to come from developed nations like Canada, like the United States, like western Europe, to deal with HIV/AIDS in the least developed countries of the world. They are not going to be able to solve the problems on their own. They're not going to be able to solve the problems through access programs, through CAMR and those issues, because there's just not enough money to pay for the drugs, to pay for the nurses.

The Chair: Okay, thank you.

We'll go to Mr. Van Kesteren.

Mr. Dave Van Kesteren (Chatham-Kent—Essex, CPC): Thank you, Mr. Chair. I didn't think I was up yet, but that's good.

Thank you all for coming.

This is interesting. I feel kind of bad for you. I'll tell you why I feel bad. You're being browbeaten because you happen to be companies that make a lot of money doing something right. And if you hadn't done those things right, we'd still be in the quandary we were in 15 to 20 years ago, when AIDS first.... So I don't think it's really all that fair to lambaste you about those things, but as I think Mr. Shipley said a little while ago, what we're trying do is to find out why Canada hasn't brought this about.

We have this wonderful idea—I think they call it Mr. Chrétien's promise to Africa. It was a wonderful idea, but it's just not materializing.

I can understand profit, I really can. It's what drives us. I was just saying to my colleague, it's not fair to suggest that your company has to provide all the answers. If we want to do that as a country, we need to shell out the bucks, to say it very bluntly.

I heard some charges, and I want to give the pharmaceuticals a chance to respond. I don't think they really had that chance.

First of all, the NGOs and the generics are opposed to the requirement to first seek voluntary licence. In your opinion—and I have a few questions, so maybe you could just answer this quickly—why is this requirement needed? Is it conceivable that a voluntary licence would be granted?

● (1650)

Mr. Terry McCool: There are a couple of points. In the spirit of transparency, companies should be notified if you're going to go to that extraordinary step of overriding patents to create compulsory licence. I think out of due process you have a right to know. I don't see any reason why, if the generic has a country identified through the WTO, that a voluntary licence from our industry would not be issued.

Mr. Dave Van Kesteren: Do you hear that, Mr. Williams? So this can be done. There may be some changing of the act. Maybe we can just make it a little bit more simple, but it's not inconceivable that licences would be granted.

Mr. Russell Williams: Frankly, I think the act is more straightforward than some people are saying. It is straightforward. Some people may choose to try to complicate it, but it doesn't have to be complicated. There are basic questions that could be answered. Absolutely, I think this all could work, and as I said from day one, we have been supportive of the principles of this act.

Mr. Dave Van Kesteren: I'm going to give you a chance to answer this question too, because I think I understand the reasoning, but why do you want the identity of the country seeking the drugs?

Mr. Terry McCool: That's a WTO requirement that 146 countries signed on to, that they needed to notify the WTO that they had insufficient manufacturing to produce these kinds of drugs. The suggestion was made that Canada should go to the WTO and change this agreement of 146 countries. Those negotiations are tough enough to do in the first place. I don't see that necessarily happening. But that's a WTO requirement, and Canada has respected those WTO decisions in terms of drafting the legislation for this.

The only thing I would add is, in all fairness, everybody had a chance to negotiate with the Canadian government for, I think Brian said, 15 months, but everybody was at the table, everybody knew what they were talking about, and everybody tried to simplify the process in the best interest of trying to get products shipped to Africa.

I think one question that wasn't answered was whether there was that much of a supply here in Canada, through the generic industry, many of whom do not have manufacturing here. There are a couple of major companies—Apotex is one—that could actually participate in this bill, but I think there was an assumption that we had this big generic industry that was going to jump on this and participate, and I don't think that's possible.

Mr. Gregg Alton: Yes. If I could, I'll jump in.

I think from our point of view at Gilead, our goal is actually for us to work directly with governments throughout the world—you call it voluntarily, but not in the TRIPS terms of a voluntary licence—and work out our arrangements. That is our goal, and that's what we try to do as a company: balance our intellectual property with the needs of patients and access to our products.

If there were ever a case where there was a need for a legislation-like hammer or the flexibility in TRIPS, I would feel, from Gilead's point of view, that we had failed as a company in meeting the needs of these countries throughout the world. We really do think that the requirement to identify the country and have our request come forward is important. Because we'd like to understand if we're not meeting those needs, and we'd like the ability to talk to that government and try to work out an arrangement whereby we can provide our drug to them through our systems, the systems we've put in place.

We have been successful every time doing that. I think that should be the goal. The goal should not be to break patents. The goal should not be to use CAMR. The goal should not be to use the flexibilities in TRIPS. The goal should be for the research and development industry to have responsible pricing mechanisms that allow access to their products by the developing world.

Mr. Dave Van Kesteren: Okay.

I have a little one, just a little one.

The Chair: Just a little one, again, yes, all right.

Mr. Dave Van Kesteren: I have to get this off my chest, because I really have to find out what's going on here.

I'm just speaking for myself, because it's in the back of my mind. Is there a possibility that African countries really are...? I mean, they're concerned about these things, but we're talking about.... Mr. Shipley was mentioning malaria, for instance. They love our good intentions, but would they want to see more help, possibly, to improve their health? We don't have tuberculosis in this country because our health care systems are much better. Is that a reality, possibly?

● (1655)

The Chair: I don't know if that qualifies as a little question.

Members, we're all going way over time, and we're going to run out of time for members' questions.

Who is that directed to, Mr. Van Kesteren?

Mr. Dave Van Kesteren: Anybody. If it's not legit, don't even jump in. But is there a possibility that third—

The Chair: Okay, Mr. Alton, I'll let you address this.

Mr. Gregg Alton: I think I do understand the question.

If you recall my testimony, I talked about countries making HIV care a priority. We talk a lot about what we believe is needed in Africa and what Africa should be doing with their health care systems. That may not necessarily be what they want to do. They may be more focused on clean water. They may be more focused on maternal health care. They may have other priorities that rise above HIV. So we need to be very careful in assuming that what we think they should be doing is what they actually want to do.

The Chair: Okay, thank you.

We'll go to Mr. Masse.

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

There was a lot of rhetoric about this bill when it was brought forth, so I think we own this collectively, or there is a responsibility to see it work. All you have to do is go back to look at the Hansards for this committee, Hansards for the House of Commons, and public statements. These are international comments that have been discussed, and at the same time, we're still not getting the result. I mean, we all understand. Nobody's naive enough to think that if we just actually produce cheap medicines it's going to solve the problems of Africa or is going to treat tuberculosis in other developing countries. For heaven's sake, the bill is even named for Africa, when it's about the entire world. That's the politics of it. But I guess the point is where do we go from this point?

I'd like to hear from each group in terms of.... I don't know if Rx and D will just stay the course. That's fine. But I'd like to know what you need to have this work. Mr. Alton has also given two suggestions that we've heard before from other groups with regard to duration of licence and the forecasting requirement, two things that I think are very important.

I'd like to hear from each organization where we go from here, in terms of solutions, to make it work for you.

Mr. Jim Keon: I would agree 100%; I think it is important that the legislation operate. Again, I would say the brand-name companies do not need this legislation. If they want to donate medicines, they can do so now without this legislation.

This legislation is intended to generate competition, because it has been shown time and again that new prices come down when an Indian generic company or someone else has the product and is ready to offer it to a government. That's what makes the price come down.

We agree with the two recommendations from Gilead in regard to removing the time limitation on the licence. I think that would be very important.

As Jack said, there is a real political problem with countries self-identifying. We would like to see that requirement removed, or limited in some way. We would like to make the licence essentially an automatic licence, to remove and limit to the extent possible the need to negotiate with the brands.

As well, we would like to remove the requirement that there only be one country at a time, for a maximum amount of product. We need to have the right, if we're going to invest $2 million, to make this product for a long period of time, to ship it wherever it's needed to whoever needs it.

We would also like to remove the potential legal liability that our companies face if the product is inadvertently diverted once it's beyond our borders. It's unrealistic to think that a generic drug company, once it sells a product to Oxfam or MSF or someone else, can then control the product through all the channels.

I don't think diversion back to the western world is really an issue. If you take the Apotex product, for instance, it's not legally available in the western world, so if it showed up there, it would immediately be caught and its sale would immediately be stopped.

So the anti-diversion is also a problem.

In our brief we have outlined six or seven significant changes we would like to see made to the bill. We think if those changes were included, the bill would be significantly improved.

Mr. Jack Kay: I think it's important, when you're making policy such as this, to really understand that this is an issue for the Canadian government, not an issue for the generic industry. If in fact we want to make these products available in an affordable manner to these countries in order to save lives, we have to come up with a policy that the generic industry can take advantage of.

And it has to be simple, or I will not, and neither will any of the other generic companies operating in Canada, use our resources to make available products on which we're not going to make any money. We'll do it because it's the right thing to do as a Canadian company, but you have to make the policy such that it works easily.

● (1700)

Mr. Brian Masse: Mr. Alton.

Mr. Gregg Alton: I have offered a couple of suggestions, which you identified before, so I won't repeat those. I would like people to look at the act as a safeguard to ensure that patents are being used responsibly, to ensure that the R and D industry is doing what it needs to do to make sure its products are affordable in the developing world. I don't think the act should be looked at as a mechanism to override patent protections.

We are very committed to access in the developing world, as is our industry. We spend tens of millions of dollars a year in the developing world running clinical trials to determine the appropriate use of our products, as well as through our programs, which we operate at substantial losses. This is something we are committed to and will remain committed to, and we want the opportunity to work in this area.

Mr. Russell Williams: One suggestion is that I want to inform more people what it is, so that it can work. And I'd like us, once we start a process, to run the process all the way through to make sure it is actually.... Before we decide what's broken, let's see what part doesn't work. Let's educate people.

Terry?

Mr. Brian Masse: To be fair, Mr. Chair, I think I'd like to record a question here for the committee; I think it would be helpful. What we're hearing is different from what was presented by government officials.

The question I would ask that this committee has heard is how much in financial and time-allocated staff resources has been spent by the government agencies on CAMR since its passing in Parliament?

I think that's important, because we're hearing some testimony that I think needs to be examined. I would hope that information would come back to this committee. I ask the committee members here to unanimously support this as a request, from all the agencies that presented to us last Monday.

The Chair: Is that a question you're putting before the committee, or...?

Mr. Brian Masse: I'm just asking the members to support this so that we could get that information.

The Chair: Sure.

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

Do I have any time left?

The Chair: Well, everybody has gone over. You're at six minutes and thirty seconds, so I would say not—unless you have a very brief question like Mr. Van Kesteren's.

Mr. Brian Masse: No, Mr. Chair, I would just like to thank the witnesses.

I know it's been difficult, some of this stuff, but if we come back and have to review this legislation in another three years from now, and we're in the same situation right now, quite frankly I think it's blood on our hands. Because that's what's going to happen. After the three-year review that's mandated to happen right now—it was amended by this committee because of the urgency of the matter—if we come back after three years again and nobody has used this tool, then it's been useless.

Thank you, Mr. Chair.

The Chair: Okay, thank you.

Mr. Shipley.

Mr. Bev Shipley: On a point of order, I'm wondering if we could have Brian's request again, just so that everybody understands it.

Mr. Brian Masse: Sure, Mr. Chair.

How much in financial and time-allocated staff resources has been spent by government agencies on CAMR since its passing in Parliament? Those would be directed to the four agencies that presented in front of this committee on the first hearings on Monday.

The Chair: Is that okay?

Mr. Bev Shipley: Yes. I just wanted to be sure of what it was.

The Chair: Okay with that, or...?

Mr. Colin Carrie: Mr. Chair, I'm just wondering if this might be a huge thing to undertake by Monday.

Are you flexible with the time?

The Chair: Are you asking for this for Monday?

Mr. Brian Masse: No, no, I'm asking for it so that we can help write a report. I would imagine that these agencies would have some basis of allocated time resource and management they'd be able to put forth on this issue. I mean, it's not that hard a question.

The Chair: Okay.

Just for future, Mr. Masse, perhaps we could inform the chair so that we might be able to get agreement rather than taking up the time of witnesses and other members.

Monsieur Crête.

[*Translation*]

Mr. Paul Crête: I'd just like to say for the committee's information that they likely had to answer that question about two months ago, during a consultative process. I've received some documents to that effect. Therefore, the government should easily be able to produce this in fairly short order.

[*English*]

The Chair: Okay. Well, if we could have....

Mr. Masse, if you could submit the question to the clerk, we will submit that to the four departments.

We will go now to Mr. Brison.

Hon. Scott Brison: This is just a question on a policy that would achieve the end that everyone is seeking.

Recognizing that the R-and-D-based pharmaceutical industry is providing drugs at cheaper prices, in certain cases in the developing world, if CIDA were to approach the pharmaceutical industry and say that these are the drugs we need for these countries, and agree that we would pay for them, would the R-and-D-based pharmaceutical firms offer the drugs at cost? If the concern is patent protection, if the concern is the potential loss of the integrity of the patent system, would the R-and-D-based industry provide, at cost, drugs to the developing world if CIDA, acting on behalf of the developing world, were to offer to buy them?

● (1705)

Mr. Terry McCool: I think in the majority of cases, because of preferential pricing, there exist either at cost or below cost in the least developed countries. They're usually either at cost or have a very small markup in the developing or more developed countries, with the anticipation that in the developed world they're going to pay the full price.

So as long as we encourage a preferential pricing system where the products don't get diverted back into developed markets, I think the industry is willing to come to the table. But what you're talking about is increasing this global pool of funding to purchase pharmaceutical products. That can be brand or generic. I think there would be certainly an interest in doing that, but I can't speak on behalf of the government's willingness to do that.

Mr. Jack Kay: If that were correct, there would be no need for this legislation.

Mr. Russell Williams: Yes. And that's happening already in many...before CIDA. In terms of your question about CIDA, there is preferential pricing, at cost or free.

So we are interested in doing that and we continue to be interested in doing that, with whatever partnerships. I think CIDA could be helpful in terms of this mandate of making sure that people understand about this bill. They could be helpful in communicating that.

Hon. Scott Brison: MSF's report on drug prices—I'm untangling the web—indicates that in a lot of cases the companies that actually hold the patents are offering low-price medications in the developing world already. It's not that they're not doing that currently.

Are you saying, Mr. Kay, that the only companies that are providing low-cost medicine to the developing world are the generics?

Mr. Jack Kay: No, sir, I am not saying that. All I'm saying is if that in fact is correct, that the brand industry is offering these products to the developing countries, there would be no need for our organizations such as the World Health Organization or MSF to come to the generic industry and ask us to provide these products.

Mr. Gregg Alton: To answer your question directly, the answer from us is yes, we would make it in Canada and we'd provide it at cost. In the least developed countries you have the other pricing providing the materials for middle income markets. I'd also just point out that to my knowledge there's not one HIV product that is in need in the developing world that cannot be manufactured in India.

Hon. Scott Brison: Some witnesses have referred to the cost of the manufacturing issue in India and the generics in India and the low cost. Is that part of the reason why we're having a problem making this legislation work, the fact that we're seeing the low-cost generic manufacturers from India actually produce generics lower and more competitively? Is that part of the problem?

Mr. Jim Keon: That is part of the problem. The other issue has been that in India they have not faced patents, so they were able to go ahead and make a product. And again, you've heard the difficulties that Apotex had in getting through the regulatory and legal requirements in Canada. They don't have any of those issues in India. Yes, cost is an issue, but so also are the legal difficulties.

Earlier someone mentioned the manufacturing capacity in Canada. Apotex itself—and if Jack wants to speak to this, he can—has more capacity to manufacture medicines in Canada than all of the brand-name industry combined in Canada. We have about eight or nine companies that have major manufacturing facilities on the generic side. That is why Canada wanted to have this legislation, because we do have a robust generic drug industry.

● (1710)

The Chair: Thank you, Mr. Brison.

Mr. Carrie.

Mr. Colin Carrie: Thank you very much, Mr. Chair. You have my permission to cut me off if I get too long-winded.

I do have a couple of questions left. One was for the Rx & D guys. Many NGOs in the generics believe schedule 1 should be eliminated. In your opinion, what's the value, if any, of maintaining schedule 1?

Mr. Terry McCool: In our opening comments we addressed that a little bit. The value in schedule 1 is that it addresses the intent of the legislation and the intent of the WTO decision, which was to address the very serious diseases, such as HIV/AIDS and malaria and tuberculosis. Having no list would mean that there's a potential for those diseases to be ignored while you try to copy drugs in other categories where they could be either more profitable or more broadly used. So it was really an attempt to define what were considered emergency-type medications.

Mr. Colin Carrie: Thank you very much.

The second question is for Mr. Alton. We in the government are trying to get an idea of the big picture of things. We see this legislation and we're dealing with CAMR right now. We're trying to figure out whether the legislation is broken, needs fixing, or needs a little bit of tweaking. The bottom line is this. How are we going to get out and help the people who need it?

I was wondering, let's say you're the health minister of Uganda right now, and you're given a budget of say $10 million for your entire country, and you're sitting around thinking how you are going to spend that. Are you going to be thinking of CAMR at all, or are you going to be thinking of things like clean wells, infrastructure, educating more doctors, educating more nurses, providing infrastructure there? What would you be doing right now if you wanted to address western countries and ask how they can best help you? What would be your opinion on that? Because this is driving me crazy.

Mr. Gregg Alton: I can't speak for what a particular minister of health may want to be doing in a particular country. To start off, I'd say $10 million would not be nearly enough to deal with the issues, but assuming that they had resources to develop health care, they're going to prioritize their health care and they're going to determine how much they want to prioritize to HIV and to the other diseases they're dealing with, whether it be tuberculosis, malaria, dysentery, whatever it may be. I

In the area of HIV, where we've seen countries be successful is when they put together national HIV programs. This is not dependent on the economics of the country, but it's actually the prioritization they put in. Botswana is a very good example. Botswana has done a fantastic job in reducing the HIV rate in their country by actually putting together a very progressive program, tapping into the international funding that's available and really making it a priority of that country to deal with it. I think Brazil and Thailand are other very good examples of where they've actually done a very good job of dealing with HIV. Other countries with similar economics have done a horrible job of actually managing the issue. They need to step up and do more, if they want to, in that area.

The Chair: Thank you, Mr. Carrie.

We'll go to Mr. McTeague.

Hon. Dan McTeague: Thank you.

I want to build on the beginning of Mr. Carrie's questions.

Mr. Kay, at the outset of this presentation you talked about the need for countries to be specific and to identify themselves. I have no doubt in my mind as to the reputation of a corporation or group or NGO like Médecins Sans Frontières and their good work.

I was speaking to their founder this weekend, Richard Heinzl, who is still shaking his head that we can't seem to break through on this. In his commentary, a company or an organization such as MSF can negotiate a contract and go to Apotex and make a solid argument for the purchase of these products to actually provide necessary medicines to those individuals, but is blocked by the brand-name industry because they do not reveal the country. Is this correct?

I want to ask Mr. McCool and Mr. Williams.

Mr. Terry McCool: It's in the legislation and it's also in the agreement of the WTO. It's not blocked by us at all.

Hon. Dan McTeague: A country would then have to declare beforehand for safeguards? Is this why the block?

Mr. Terry McCool: A country just has to declare that they have no ability to manufacture the drug, that's all. They just have to send a letter to the WHO and post it. That's all they have to do.

Mr. Gregg Alton: One thing we need to understand is that a lot of times these governments actually do not want a compulsory licence. They would rather work things out. The NGO community has had a very vocal public campaign to break intellectual property rights throughout the world. They want to do that. They claim victory when a government threatens a compulsory licence, and they claim failure when it doesn't do so. This may be a situation where the NGO is actually trying to encourage a compulsory licence, trying to encourage the use of CAMR, when the government itself is not in a position where it wants to do that.

● (1715)

Hon. Dan McTeague: Mr. Alton, we all had the embarrassing spectacle—all of us, I think, would agree at this table—of one country having to be dragged into court because it decided it wasn't going to necessarily follow the rules in order to assist its people.

But I'm asking the question: is it necessary, in your view? Why would you want to defend having the country name itself if there are existing safeguards to protect abuses, or do you actually believe that without naming the country there will be abuses?

Mr. Gregg Alton: I think there will be abuses. A lot of the activist and NGO communities have made it very clear that they do not want to see patents enforced outside of the western world. They will do everything they can to see those patents pushed aside. I think this could be a situation—I don't know the particulars—where there would be the opportunity for the R and D industry to go in and work out an appropriate arrangement with this government. This is taking that ability away.

Hon. Dan McTeague: What if the Canadian government knew what government was there and had a quiet word with Mr. McCool, Mr. Williams, Mr. Kay, and Mr. Alton and said, look, we have extremely good connections with this particular country, we believe this to be a bona fide legitimate request, and we believe this particular company may be able to provide what is needed there? I think there is also the question of some nations not wanting to bear the stigma of declaring themselves in that situation. I don't know the cultural sensitivities, but I do know of the imperative of trying to get those drugs there.

Mr. Alton, I appreciate your comment, but frankly it's one of the many reasons that are being used right now. We can assign or deride the NGOs as we wish, but the 300,000 children who died last year in Africa speaks volumes to me as to our inability.

I'm wondering, if the Canadian government through a review of this legislation were to make a direct undertaking to the government that was looking for this and the request was legitimate, and with a certificate by the Canadian government, would you then accept that? Do you think that would be an acceptable means of getting around that so we can help companies like this provide drugs to help save lives?

Mr. Gregg Alton: I would ask if we would have the opportunity to engage in discussions with that country to find out what the challenges are for that country to access our medicines to put their patients on the drugs, and have the opportunity to try to work out arrangements with that country directly.

Hon. Dan McTeague: Why aren't you doing it now?

Mr. Gregg Alton: We are doing it now.

Hon. Dan McTeague: But there are people dying in those countries.

Mr. Gregg Alton: I'm saying that prices and patents are not what is causing these patients to die.

Hon. Dan McTeague: Yes, Mr. Williams, and I apologize, I called you Mr. Russell earlier. I didn't have my glasses on.

Mr. Russell Williams: I'm used to it, don't worry. I'm going to change my name to William Russell.

To your question, and it's an important question, it seems to me some basic information is important. I understand the sensitivities you're trying to get out. We are very touched by this humanitarian crisis. We have to deal with this, and we're working on it. I'm not going to spend more time on this, but we are actively doing it, and we're going to continue to do it. We all should do more, and we should be comprehensive.

But we're always trying to get that equilibrium between intellectual property protection and access, and it seems to me that if we're going to change that balance, then some basic principles to make sure there aren't diversionary activities are to know what country is asking for it, to know what quantity, and to know who is going to use it. Those are pretty basic kinds of things. If there's a way to get at it that builds in some flexibility, we should look at it, but those basic principles, of getting those four questions answered, I think are pretty fundamental.

The Chair: Sorry, I think Mr. Keon wanted to jump in.

Mr. Jim Keon: I was just going to say, in line with what Mr. McTeague said, again, the brand-name companies own these medicines, they have the patents, now they can go to any country they want and offer the product at any price. Why did the developing countries want the system under the WTO? Why do they support the Canadian legislation? Why would they like to see improvements? It's because they're not getting the product as often as they want at the price they want. They want more competition, they want someone else to bid on their tenders. That brings prices down; that's what they need, and that's what this legislation is intended to do.

The Chair: Mr. McCool, briefly then, if you want to respond.

Mr. Terry McCool: To clarify one of Mr. McTeague's points. If you're a least-developed country that's not a member of the WTO, you can come directly to Canada, you don't have to post at the WTO. It's only for WTO members, and that's consistent with every country that's introduced this legislation.

● (1720)

Hon. Dan McTeague: If you come directly to Canada, you come directly to—

Mr. Terry McCool: If you're not a member of the WTO.

Hon. Dan McTeague: All right. Thanks.

The Chair: Okay. Thank you, Mr. McTeague.

We'll go to Monsieur Arthur.

Mr. André Arthur (Portneuf—Jacques-Cartier, Ind.): Thank you, Mr. Chair.

I'm always amazed at the ability of a government and a Parliament to complicate things. When you multiply that by the number of countries that are members of the WTO, I guess we now realize that the possibilities are infinite.

We've taken the goodwill of the world and put it smack in the middle of the minefield of a war between the generics and the brand names, and then we should be proud of that—something's wrong.

Then there's also this complicated relationship between pills and money. Here are countries that are the poorest countries in the world and they're supposed to want medicines, but in fact they want money. If we send them money to buy our medicines, they will say it's paternalistic, that they don't want it. They want our money to build their plants to produce their medicine with our patents or our absence of patents. So at no time will we see a real order with real money for real drugs at a good price. They are not interested.

Moreover, most of those countries on the schedule are on another schedule, the schedule of the most corrupt states in the world. Here we are, with our goodwill and our minefield, trying to be asked to produce some drugs for them, then we'll give them a good price. I'm not sure they're interested in buying drugs. They will take everything we give them, but they would still prefer money because it's so much easier to put money in a Swiss account than in pills.

Mr. Kay, you told us about your nasty experience with a country that did not want to be identified. This country, was it a real order they were ready to pay for when you invented the triple combination of peppermint you have on your desk? Was that a bona fide order or was it just talk?

Mr. Jack Kay: My belief is, in talking with the people from MSF, it was a bona fide order.

Mr. André Arthur: That they would have paid for.

Mr. Jack Kay: That MSF would have paid for.

Mr. André Arthur: But not the country; they wanted a gift.

Mr. Jack Kay: Not the country, that is correct.

Mr. André Arthur: How can that be fixed? We have one government complication, multiplied by all the governments of the WTO, to have an international regulation that's inapplicable, and then we're here, all Canadians of good faith, trying to find a solution. Isn't the solution much more simple: that the Government of Canada will buy drugs in Canada and ship them to whoever over there wants to get the drugs?

Today you gave us a magnificent demonstration that there are no solutions. You will never agree on anything, and you don't want to agree because it's contrary to the real interests of you people. You do not need that thing, that complicated thing. You are much more at ease sending your brand-name medication over there, free of charge. You are much more occupied producing drugs for the Canadian market and you don't care about Africa when the bottom line appears. So there's no solution.

Is there a solution?

Mr. Jack Kay: First of all, if I didn't care, I would not have spent $2 million in developing these products to be shipped to those countries where people are dying. We did it because as a Canadian company it was the right thing to do.

I do agree with you that, as one of the other members stated, maybe the right way to handle this is for CIDA to be buying products, whether it be from a Canadian generic company, whether it be from my friends from the brand industry, or whether it's even from companies manufacturing generics in India, in order that Canadians do the right thing in helping to save lives.

● (1725)

The Chair: I have Mr. Williams now.

Mr. Russell Williams: Mr. Arthur, I think you actually highlighted a number of the problems we're talking about. One of the things we try to say is that there are many ways we should try to find a solution. There's not one solution; there are many solutions. If we try to think there's one panacea that's going to fix everything, we're wrong. So whether it's preferential prices, cost-free generics, it's all part of that question.

There's another more fundamental question about clinics and health care and transportation. I think John Kelsall is the president of Health Partners International Canada. He came here last week and talked about this as actually even being a transition. What we should be doing is trying to train and to help people develop their own manufacturing capabilities overseas, to work on their health care system, etc.

So I'm actually thinking there are many solutions and we should build on each and every one of them. We shouldn't be looking for just one answer.

The Chair: Mr. Arthur, do you have a very brief question?

Mr. André Arthur: No, sir. Thank you very much.

The Chair: We're at the end, so I will have a few minutes for a few questions for the chair.

First of all, I want to thank you all for coming in today and for discussing this issue in this manner.

I do want to touch upon a number of issues.

First of all, in Mr. Alton's presentation, he talks about the forecasting and duration of a licence. I'm assuming the generics are supportive of what Mr. Alton is recommending in both of those things, with respect to removing the forecasting requirement and that CAMR should not prescribe a specific duration of a licence.

I want to get Mr. Williams or Mr. McCool to respond on the forecasting and duration of a licence.

Mr. Terry McCool: I think the duration of a licence is reasonably generous. It's two years with a two-year renewal, so it's actually a four-year licence. I think part of the rationale behind that is this. If prices drop, if new technology comes on that's a little better, do you really want to tie governments into unending contracts without a way out? I just think there's probably a process that needs to be in place that respects the legislation that's been passed.

The Chair: And forecasting?

Mr. Terry McCool: Forecasting is a challenge because they don't know how many people they're going to treat in some of those countries. It's all dependent on the number of health care centres and nurses, on being able to get into rural communities, the infrastructure, transportation, and things like that. I don't know how you forecast that in sub-Saharan Africa, I really don't.

The Chair: Thank you.

I also want to get your response in the generic presentation. In the additional information they've provided, they said that with the WTO decision, they do have to satisfy themselves that the importing countries made the required notification of TRIPS, that they needed a product. I think the generics are arguing that this notification can be met in a much easier and simpler form than what has happened under CAMR now. If there were some form of notification, but if it were simplified, would you be in favour of that, or do you believe the notification in CAMR is the minimum standard?

Mr. Terry McCool: I think it's pretty minimal notification, to be honest with you.

The Chair: It's a minimal standard.

Mr. Alton, do you have a position on that?

Mr. Terry McCool: Yes, and I've stated before that I think the notification requirement is very important. I don't think it imposes an undue burden.

The Chair: So you would not change the notification requirement?

Mr. Gregg Alton: No, I think that's critical.

The Chair: Okay.

With my third question, I'm try to clear this up. There are a lot of people who say this legislation doesn't work, it's broken, it's a disaster, it's just terrible. Yet one of the challenges for the committee is we don't actually have very many case studies where we can say it has not clearly worked in this case or that case. My understanding from the officials we had here at the first session is we have two cases that we can actually look at. One case is public; the other case is not.

I want to try to understand for myself what happened or did not happen in the case with respect to Apotex and the drug. My understanding is that it was actually three patent holders, but Mr. Kay mentioned it was four patent holders. Based on the research I've been given, my understanding is that Apotex submitted the product for Health Canada approval under CAMR in December 2005. The approval was granted in June 2006. In August 2006 the drug received pre-qualification status from the WHO. Apotex began discussions with the drug's patent holders in June 2006, but because of the complexity of the process, nothing has moved since.

I want to try to understand what is meant by the complexity of the process. On reading this background, which was provided by the researchers, it seems to me the process was moving along and then it stopped.

So, Mr. Kay, explain to me why the process stopped.

● (1730)

Mr. Jack Kay: It's because the country that MSF was buying the products for did not want to be identified. It's that simple.

The Chair: The country did not want to be identified in any way.

Mr. Jack Kay: That is correct.

The Chair: Mr. Williams or Mr. McCool, do you want to respond to that?

Mr. Russell Williams: As I've mentioned several times, there are four basic criteria that need to be responded to in the first phase and in the second phase. We believe they are quite straightforward.

My understanding is that in the second phase, if the first 30 days don't work, there would be a movement fairly quickly to compulsory licensing, if all criteria were completed. I don't know why that stage still hasn't been tested.

The Chair: Do you agree with what Mr. Kay said that the reason the process stopped is because the country did not want to be identified? Is it true or is it not true?

Mr. Russell Williams: I cannot determine the reason that Apotex didn't continue.

The Chair: He's saying this is the reason that it did not continue. I don't know. It's why I'm asking.

Mr. Terry McCool: We wouldn't know the answer to that either.

The Chair: It seems to me that we've hit an impasse where if no country actually wants to be identified, this legislation will never work. What I'm looking for as the chair, and I think what all members are looking for, is a process that will work here.

The NGOs are clearly saying the NGOs should be allowed to purchase the medicine, and then they can provide it. I know the generics would be in favour of that.

Mr. Alton and Mr. Williams, do you want to respond?

Mr. Russell Williams: I understand your question is focused on the claim that it was uniquely that a country would not identify itself.

There are other lists, and I think Madam Brunelle listed a number of other areas where people speculated why it doesn't work. One of them from Industry Canada was in fact on the cost of generics in Canada. There are a number of areas on why it may not work.

Mr. Gregg Alton: I have one observation on this. We're talking about why CAMR is not working. Mr. Kay has come up with an example, where a country that appears to have a substantial need for a product is not even willing to identify itself to avail itself of a low-cost generic.

I think it highlights a broader problem, which is the true desire of these countries to deal with HIV. If they're not even willing to be named to deal with their patients and the 300,000 children who are dying, it's a real problem.

The Chair: My time is almost up, Mr. Kay, but I think you wanted to respond. Could you tell me why the country did not want to be identified, if you know that?

Mr. Jack Kay: I cannot answer that because I don't know. I think several different hypotheses have been put forward as to why the country didn't want to be identified.

But I'd like to comment on the fact that generic pricing in Canada is an irrelevancy as far as this one order goes. We are providing it at 39¢. MSF was happy to buy it at our cost.

The Chair: Well, I'd love to continue this discussion, but I've run out of time.

I want to thank you all for coming today. I appreciate your time. I think it was very informative, and we appreciate that.

Members, we will have a meeting on this in a week and a half. I'd encourage you to give your thoughts to the researchers as soon as possible so that we can have a fruitful discussion at that point on possible report recommendations, whatever the committee decides to do.

Thank you all for coming.

The meeting is adjourned.

Published under the authority of the Speaker of the House of Commons

Publié en conformité de l'autorité du Président de la Chambre des communes

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