

Also available on the Parliament of Canada Web Site at the following address:

http://www.parl.gc.ca

# **Standing Committee on Public Accounts**

Monday, February 12, 2007

#### • (1530)

# [English]

The Chair (Hon. Shawn Murphy (Charlottetown, Lib.)): I call the meeting to order. I want to welcome everyone here. *Bienvenue à tous*.

Members, witnesses, we're here today to deal with chapter 8 of the November 2006 *Report of the Auditor General of Canada*, "Allocating Funds to Regulatory Programs—Health Canada".

We have with us, as usual, Sheila Fraser, the Auditor General. She is accompanied by Ronnie Campbell, the assistant auditor general, and Louise Dubé, a principal. From the Department of Health we have Mr. Rosenberg, the deputy minister; Susan Cartwright, the associate deputy minister; Neil Yeates, the assistant deputy minister; Susan Fletcher, assistant deputy minister, healthy environments and consumer safety branch; and Richard Charlebois, director general of the financial operations directorate.

Before I start, I understand Mr. Wrzesnewskyj has a motion and Mr. Williams has an opening statement.

#### Mr. Wrzesnewskyj.

Mr. Borys Wrzesnewskyj (Etobicoke Centre, Lib.): Thank you, Chair.

I have a motion, and it will be provided in both official languages to all the committee members at the end of the meeting. The motion reads:

In order to ensure that the Public Accounts Committee is fully able to get to the bottom of the serious criminal issues surrounding the findings of the Auditor General in Chapter 9 of the Auditor General's Report of November 2006 - Pension Insurance Administration - Royal Canadian Mounted Police, I move that the following persons be asked to appear as witnesses before the Public Accounts Committee on February 19, 2007: Staff Sergeant Ron Lewis: Public Service employee presently, but formerly with the RCMP, Denise Revine; Chief Superintendent Fraser Macaulay; Staff Sergeant Steve Walker; Staff Sergeant Mike Frizzell; and Assistant Commissioner Gork.

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

We'll debate and vote on this motion on Wednesday.

Mr. Wrzesnewskyj, you're just giving us names here. Is there any possibility, to deal with this intelligently, that you can provide—not now—the members of the committee with some kind of summary of their relevance, what you expect them to say? My point is that you're only giving us names. Perhaps you wouldn't mind giving us a three-line summary as to their relevance.

Mr. Borys Wrzesnewskyj: I'd be more than happy to, Chair.

**The Chair:** Not now. We'll give it to the clerk and the clerk will circulate it. We will vote on this too.

Mr. Borys Wrzesnewskyj: Thank you.

The Chair: Mr. Williams, you have an opening statement.

Mr. John Williams (Edmonton—St. Albert, CPC): Thank you, Mr. Chairman.

Before the meeting really gets under way and before Mr. Rosenberg gives his testimony, I'd like to clarify for the record that Mr. Rosenberg never refused to appear before this committee, as we were discussing last week. Our discussion during the February 7 meeting may have inadvertently conveyed that message. So in fairness to the deputy minister, I believe the committee record should now clearly indicated that this was not the case. In fact, he was only asked to appear after the official notice had already been sent out last Wednesday. Once it was clarified that the committee wished to hear from Mr. Rosenberg, the deputy minister himself, he immediately made the necessary arrangements to be here, and we all thank him for that. We appreciate it.

**The Chair:** Mr. Williams, you're quite right. Perhaps I may add that it probably arose from a misunderstanding. I think we're all feeling our way with this new Accountability Act. We do expect the accounting officers to be here. To Mr. Rosenberg's great credit, I understand he had a trip to Vancouver today and he cancelled the trip to be here with the committee.

Another thing we have to do a little better as a committee, and sometimes it is difficult with our schedules that are always moving, is do a better job in giving witnesses notices of the meetings. I know the Office of the Auditor General knows they're going to be here, they have these schedules, but the other witnesses, especially the accounting officers, have to get more notice before the meetings.

We apologize for that, Mr. Rosenberg.

I want to again welcome everyone here. I understand you, Mrs. Fraser, have an opening statement, and you, Mr. Rosenberg, have an opening statement.

I invite you, Mrs. Fraser, to address the committee now.

# Ms. Sheila Fraser (Auditor General of Canada, Office of the Auditor General of Canada): Thank you, Mr. Chair.

We thank you for this opportunity to present the results of our audit on allocating funds to regulatory programs at Health Canada. As you mentioned, I'm accompanied today by Ronnie Campbell, assistant auditor general, and Louise Dubé, principal responsible for audits of Health Canada.

This audit focuses on one of Health Canada's core roles, that of regulator. Regulatory programs for which Health Canada has primary responsibility play an important part in furthering public health and safety. The audit examined three programs that regulate the safety and use of products commonly used by Canadians, that is, consumer products such as cribs, medical devices such as pacemakers, and drug products such as prescription drugs. The audit found that Health Canada does not know if it is fully meeting its regulatory responsibilities as the regulator of product safety, medical devices, and drug products.

Health Canada needs to determine the activities that must be carried out in the three programs audited in order to meet the department's regulatory responsibilities. Program managers have indicated to management that some core compliance and enforcement activities are insufficient to protect the health and safety of Canadians. At the present time the department does not know whether they are above or below the minimum level of activity required in the three programs.

#### [Translation]

Health Canada also needs to determine the performance targets for these activities. The audit found that performance indicators have been developed for the three programs, but few have measurable targets. Without targets, it is difficult to determine what a program has achieved compared with what it was intended to achieve.

Health Canada needs to determine the level of resources required to carry out the activities necessary to meet its regulatory responsibilities. We found that Health Canada's system of allocating its resources among various branches and programs is based on the previous year's funding rather than on plans and sound financial and performance information.

### • (1535)

## [English]

The audit found that the budget for core funding for the three programs audited has significantly decreased over three years—10% for the product safety program, 32% for the drugs program, and 50% for the medical devices program. Furthermore, the total funding allocated to two of these three programs has remained constant, but the demands on the programs are increasing. This makes it difficult for program managers to fully meet the department's regulatory responsibilities of protecting the health and safety of Canadians.

These three elements together—the required activities, the defined performance targets for these activities, and the necessary resources to do this work—would provide the department with the information needed to demonstrate whether it is meeting its regulatory responsibilities and whether adequate financial resources are being allocated to regulatory programs.

# [Translation]

We are pleased that Health Canada has agreed with our recommendations and that it has already taken steps to improve its process for allocating resources. The department has redesigned the operational planning process, which, at the time of the audit, was scheduled to be implemented in 2006-07.

Because this area is so critically important to Canadians, your committee may wish to ask Health Canada to provide you with a detailed action plan and a timetable for its implementation, and to provide the committee with regular progress reports.

Mr. Chairman, that concludes my opening statement. My colleagues and I would be pleased to answer your committee's questions.

Thank you.

# [English]

The Chair: Thank you very much, Mrs. Fraser.

Mr. Rosenberg, over to you.

Mr. Morris Rosenberg (Deputy Minister, Department of Health): Thank you, Mr. Chairman. On behalf of Health Canada, I'm pleased to be here today to speak to chapter 8 of the Auditor General's report from last November.

We thank the Auditor General for her report. We're pleased she has recognized that we've already made progress in this area that we're here to talk about, which is regulatory programs.

Let me say that we agree with the Auditor General's recommendations, and that in fact the department has already started work to address some of the very issues that were raised. In light of the report, we are preparing a detailed action plan, which we would be pleased to share with the committee over the course of the next couple of weeks.

#### [Translation]

Health Canada's top priority is protecting the health and safety of Canadians. Every day, our dedicated staff work to safeguard our citizens' health and safety through robust regulatory systems. I can tell you that our safety record in this regard is one of the best, according to international standards. In fact, Canada was recognized in 2002 by the Organization for Economic Co-operation and Development as a world leader in good regulatory practice and as a pioneer in the field of regulatory reform. Health Canada's role in protecting health and safety is well recognized and supported by Canadians.

#### [English]

That's not to say we don't face challenges, but we do continue to make progress. We appreciate the opportunity to discuss our work with you here today. Our regulatory responsibilities are significant and broad. Just to give you an idea of the diversity, some of the areas of Health Canada's regulatory responsibilities include drugs, medical devices, and other health products; food; pesticides; consumer products and hazardous substances in the workplace; air and water quality; and toxic substances in the environment.

Regarding drugs and medical devices, as I mentioned before, our regulatory performance today measures up well. Let me give you some specific examples.

Through investments made in the 2003 budget, \$190 million in that case, Health Canada has substantially improved the timelines of product reviews for drugs and medical devices while maintaining high safety standards. We've cleared the backlog of reviews and are now meeting internationally benchmarked performance standards for reviews on an ongoing basis. This means that Canadians have earlier access to the products they need.

Another example is the strengthening of Health Canada's postmarket surveillance of safety and effectiveness as well as our compliance and enforcement capacity for drugs and medical devices. This was possible as a result of investments announced in the 2005 budget of \$170 million over five years.

A final example is our commitment to improving transparency and openness. We are making more information available to the public about the basis upon which decisions are taken, adverse drug reactions, and product risks, as well as increasing public involvement in the regulatory decision-making process. We've also consulted with Canadians on a new policy on public input to the health products review process, which we will be implementing in the next month.

Along with our progress, Health Canada faces a number of challenges in its regulatory programs. To name a few, the department needs to respond to rapid advances in science and technology, to expected and unexpected public health challenges, and to meet public and stakeholder expectations in terms of access, safety, and transparency in addition to increasing demands for faster product approvals and increased intellectual property protection. Our work is broadening in scope, requiring multi-departmental and multijurisdictional action.

Canada is not unique by any means in this situation. Our regulatory counterparts around the world are facing very similar challenges.

As I mentioned earlier, Health Canada is working to strengthen our regulatory systems to better safeguard the health and safety of Canadians. In describing what we're doing, I'll note some of the key actions that address the Auditor General's recommendations on improving program management and delivery. I'm grouping these into four main areas of action: program review, cost recovery, operational planning and resource allocation, and performance management and reporting.

We start with the review of our regulatory programs. We are currently undertaking comprehensive reviews of all of our regulatory programs and activities in order to define the level of activities, performance, and resources required to meet our regulatory and other responsibilities, based on the full cost of these activities. In the health products and food branch, this review is complemented by a policy review and renewal exercise for the health products and food system. Together, these reviews will help us further strengthen the regulatory system and meet the needs of Canadians in the future. In the healthy environment and consumer safety branch, a comprehensive review and assessment of our regulatory responsibilities is also under way. They also include compliance and enforcement capacities.

Second, we're updating our cost recovery regime in the health products and food branch to ensure that the department recovers a reasonable portion of its costs for regulatory programs in the branch, including overhead costs. Fees were originally set in the 1990s and haven't been adjusted since. Now it'll be integral to the consideration of any new fee schedule as to what is the appropriate proportion of resource levels that should come from cost recovery and what should come from appropriations.

• (1540)

#### [Translation]

Third, as part of the strengthening of our financial management control framework, we are improving our operational planning and resource allocation process. We are also implementing a budget management framework. This means that, once funding is allocated to regulatory programs, the department has adequate tools to compare the program objectives and expected results.

These expected results and our performance against them will, in turn, help us to make prudent future funding and resource allocation and reallocation decisions. We are incorporating directives to ensure that the department complies with the conditions and decisions of Treasury Board, and builds on improvements at the branch and departmental level over the past several years.

# [English]

Fourth, we're strengthening our performance measurement and reporting. The health products and food branch is revising its entire performance measurement framework, including performance indicators and targets for all of its regulatory programs. This new framework will be in place by April 1 of this year.

One further but very important note is that the HECSB's product safety program has also been investing resources to develop and implement an effective planning and performance measurement framework. There will be further work carried out as part of a branch-wide effort to enhance or establish appropriate indicators, baselines, and measurable targets toward tangible results. In conclusion, we accept the Auditor General's recommendations, and actions are under way to implement them. Through these actions, our intention is that our well-established regulatory systems will be strengthened.

My colleagues and I are happy to answer any questions that the committee has relating to chapter 8 of the Auditor General's report.  $\bullet$  (1545)

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

We'll go now to the first round. Mr. Rodriguez.

[Translation]

Mr. Pablo Rodriguez (Honoré-Mercier, Lib.): Thank you very much, Mr. Chairman.

Auditor General, ladies and gentlemen, good afternoon. Thank you for being here today.

Ms. Fraser, one of the comments in your presentation made me smile. You stated that:

[...] Health Canada does not know if it is fully meeting its regulatory responsibilities as the regulator of product safety, medical devices and drug products.

So the department does not know whether it is fully meeting its responsibilities. I find that comment somewhat strange. We do not usually see that kind of observation. We hear that a department is not carrying out its responsibilities properly or not at all, but we do not hear that it does not know whether it is doing so.

Could you perhaps explain that a bit, please?

#### Ms. Sheila Fraser: Yes.

Basically, our audits do not include program evaluation, and that is very clear in the Auditor General Act. We audit whether the departments have measures and ways of evaluating their effectiveness and efficiency.

So when it comes to regulatory programs, we expected that the department would know what kinds of activities it needed to carry out to meet its requirements with respect to activities; then the resources would be allocated on that basis. What we found in our audit was that the department had not specified the activities or level of activity that were to be carried out.

Mr. Pablo Rodriguez: Thank you.

At this point, Mr. Rosenberg, are you in a better position to know whether you are carrying out your responsibilities fully?

**Mr. Morris Rosenberg:** To begin with, I would like to say that there are certain activities that are ongoing, and international comparisons by the Organization for Economic Co-operation and Development in Paris show that Canada's performance is very good compared with that of other countries that regulate the same areas.

In carrying out our responsibilities from day to day we take an almost continuous risk-assessment approach. For example, it came to our attention in 2004 that there were risks involving Vioxx and other similar drugs. We took immediate action to invest resources in order to deal with the problems, to try to regulate that area, which included asking cabinet, and eventually Parliament for new resources. We make adjustments every day.

I would also say, in response to the criticism in the Auditor General's report, that we can improve our planning system. As I said in my opening remarks, Health Canada is doing a great deal to improve its planning in order to be able to determine the exact level of activity that it needs to undertake.

**Mr. Pablo Rodriguez:** On that point, I read the report and a comment on page 2 caught my attention. The Auditor General wrote: "Program managers do not always have complete information to decide on how best to allocate their resources."

A little further on, she added: "This makes it difficult for program managers to determine the level of funding each activity needs if it is to provide Canadians with the appropriate level of protection."

Has the situation improved now?

**Mr. Morris Rosenberg:** That does not mean that there are no resources. There are resources. However, it is a question of whether they properly reflect the scope of the challenges being dealt with. I believe that, generally speaking, we do carry out our mandate. That said, it is always possible to improve the way we do things.

In government, and especially at Health Canada, planning is a work in progress. I believe that we are moving forward with the changes implemented recently to respond to the Auditor General's report. In fact, we brought in changes before that. For several years, we have been working on improving our planning process.

• (1550)

**Mr. Pablo Rodriguez:** Do you have enough money? Do you want more money?

**Mr. Morris Rosenberg:** From an overall standpoint, I would say we do have enough. In cases where we find that there is more risk, there are risk management processes in the department that allow us to make adjustments.

**Mr. Pablo Rodriguez:** What I want to know is whether you feel that you have enough resources to carry out your role.

**Mr. Morris Rosenberg:** From my understanding of our challenges, I would say that we have adequate resources. But we will continue to assess whether, in the context or the environment, there are other risks. If so, we will ask to be able to reallocate resources within the department or, if necessary, request new resources from the government.

**Mr. Pablo Rodriguez:** If I understand correctly, you are working on a detailed action plan that you will table.

**Mr. Morris Rosenberg:** Yes. I intend to table this detailed action plan that will be ready by the end of February.

Mr. Pablo Rodriguez: What are the main thrusts?

**Mr. Morris Rosenberg:** It is about operational planning and a budget management framework. We want a better coordination of branches at the departmental level. In addition, the branches are making great efforts to achieve this. I could ask my colleagues who are present here, that is the assistant deputy ministers of each branch, to give you some more details on what is being done in their branch.

**Mr. Pablo Rodriguez:** I am afraid that we do not have the time. How much time do I have left, Mr. Chairman? [English]

The Chair: You have one minute.

[Translation]

Mr. Pablo Rodriguez: Time flies when you are having fun, doesn't it?

I understand that you said that you want to improve your transparency. Am I right?

**Mr. Morris Rosenberg:** Yes. For example, last year we followed a process on the Cox-2 inhibitors, namely Vioxx, Celebrex and other such drugs. A group of experts was created to investigate the matter. Up to then, it was customary to have experts discuss matters among themselves and then make recommendations to the department. We opted for a model that already exists in the United States, in the Food and Drug Administration. The public was invited to voice its opinions.

Even if such opinions are not strictly scientific, we thought that it was important to gather the comments of people who have used these drugs. Therefore, we tried to be more open and to consult the public.

Mr. Pablo Rodriguez: Thank you.

Le président: Thank you very much, Mr. Rodriguez.

Mr. Laforest.

Mr. Jean-Yves Laforest (Saint-Maurice—Champlain, BQ): Thank you, Mr. Chairman. Good afternoon, ladies and gentlemen.

Mr. Rosenberg, I heard your comments and I am comparing them to what the Auditor General said in her report. There seem to be a few contradictory points. You stated that your safety record was among the best in the world, according to international standards. On the contrary, the Auditor General's report indicates that we cannot be sure, beyond doubt, that the Canadian public is entirely protected.

Ms. Fraser's report mentions that with regard to the additional funds requested for the Product Safety Program, the program managers said that their inability to assume these responsibilities might have an impact on the health and safety of Canadians. Elsewhere in the Auditor General's report, there are some statements to the same effect, namely that the funds do not seem to be allocated to well-defined objectives. Nevertheless, you are telling us that your record is one of the best in the world. This seems contradictory, to say the least.

• (1555)

**Mr. Morris Rosenberg:** I will try to answer, but I might have to ask one of my colleagues to elaborate on my answer afterward.

Yes, I agree that we can improve our planning and funding system, and we are doing that. No doubt, we can do better. However, let us take some examples. If we look at the results, we have

## [English]

fewer safety-related drug product withdrawals

[Translation]

than in the United States, for instance.

This shows that we are doing something right. The regulations for hazardous products are different from those that apply to drugs. For drugs, there is a pre-approval system. This means that a drug cannot be put on the market before Health Canada has reviewed it.

Regarding hazardous products, things are different. Products are put on the market, and then all kinds of methods are applied, like cyclical inspections, the monitoring of complaints and communicating with regulatory agencies in other countries, to prevent the importation of dangerous products.

Our relations with producers are very important for us, and I think that their interests are quite similar to those of the government. They do not want to produce or import hazardous products, because they can incur civil or criminal liability. If we notice that there is a problem with a product, we notify them. Most of them do what they have to do. They do not market the product or they withdraw it.

Thus, we are already using all kinds of methods. We are not starting from scratch. As Ms. Fraser said in her report, improvements can surely be made.

Let me ask Ms. Fletcher, the Assistant Deputy Minister, to continue.

Ms. Susan Fletcher (Assistant Deputy Minister, Healthy Environments and Consumer Safety Branch, Department of Health): The only thing that I want to add is that besides the regulatory measures that we...

With your permission, I will continue in English.

# [English]

In addition to the regulatory measures we have for compliance with our regulations, we also measure public awareness of hazardous products and public knowledge of difficulties that products have had in the past, and what they should be aware of in purchasing products. So it's a partnership, if you will, with the public buying consumer products, and us ensuring that the products on the market are as safe as they can be for consumers.

#### [Translation]

**Mr. Jean-Yves Laforest:** Ms. Fraser, could you tell us if your audit of Health Canada was due to a request made by the committee, or was it a routine audit?

**Ms. Sheila Fraser:** No, it began with our audit of the Medical Devices Program. Exhibit 8.6 shows that we analyzed the program's funding. I think that the report states that it was in the year 2003-2004. If you look at the table, you will see that there is core funding of \$2 million and that there was also a reallocation of \$4 million, which means that there was no longer any core funding, because the other funds were taken from revenue or from special initiatives. Consequently, the regulatory program was left without any core funding. This was cause for concern. I said that I would like the department to review the way in which funds are allocated to regulatory programs within the department.

• (1600)

**Mr. Jean-Yves Laforest:** Nevertheless, your report raises safety and health issues with regard to certain programs. The funding is not always consistent with specific objectives, performance indicators.

Personally, are you worried?

**Ms. Sheila Fraser:** Honestly, I am not worried. The report states that the department is unable to determine the type and level of activities that it deems necessary for regulatory programs. This is not an evaluation issue, but we expect the department to be able to demonstrate this to us and to keep subsequent allocations of funds in line with its evaluation.

As Mr. Rosenberg said—and it is written in the report—the department does risk assessments and focuses on the areas with higher risks. Generally—and the department says that it agrees with this—we expect to have reference data on the types of activity involved in certain programs, and that the allocation of funds be done accordingly.

Mr. Jean-Yves Laforest: Thank you, I am finished.

[English]

The Chair: Merci beaucoup, monsieur Laforest.

Mr. Sweet.

Mr. David Sweet (Ancaster—Dundas—Flamborough—Westdale, CPC): Thank you, Mr. Chairman.

Mr. Rosenberg, how long have you been a deputy minister of this department?

Mr. Morris Rosenberg: It's been since December 2004.

**Mr. David Sweet:** Was your department involved in the recategorization of the 23,000 chemicals prior to 1994?

Mr. Morris Rosenberg: Yes. Those were the toxic chemicals.

**Mr. David Sweet:** I was at a meeting just this morning, and it should be noted that you have a reputation worldwide. In fact, the European Union and the United States both praised you for being on target by last September on this.

Mr. Morris Rosenberg: Those were Susan Fletcher's people.

Mr. David Sweet: Great. Congratulations on that.

However-

Voices: Oh, oh!

Ms. Susan Fletcher: I knew it was too good to be true.

**Mr. David Sweet:** —with the number of recommendations in the report on performance monitoring, targets for programs, and lack of clearly established baseline funding, it wouldn't be difficult for someone to read the report—with the amount of agreement—and think something was radically amiss in the management systems at Health Canada.

I'm wondering if you can give us an idea of how it got this way.

**Mr. Morris Rosenberg:** As the Auditor General says, what we're talking about here are management frameworks. That's what she was looking at. I think this has been a slow process of evolution that continues within the government to get sound management practices

into place, to be clearer on what priorities are—not only to be able to be clearer on a process for allocating resources internally and outside the department to those priorities, but also to be able to measure whether you're actually meeting your priorities, and then to do the whole thing again, because the environment we're in is a very quickly changing environment.

We accept the report, and this is actually very helpful to us because it focuses the mind in Health Canada, and not just in the three programs mentioned, but I think the lessons are there to be applied across the board in all the regulatory programs in Health Canada. It focuses the mind on this, and we are putting improvements in place.

But again, as I answered earlier in French, we're not starting from zero. We have started, over the past few years.... Certainly I can't personally answer on back before I was deputy, but I know, from having spoken to people, that there was a lot of work starting around the year 2000, and it has evolved slowly. Health Canada is a big, complicated enterprise. It's a bit like herding cats sometimes, and we're actually trying to develop a comprehensive department-wide framework.

So I think it started bottom-up, with work done in the individual branches. What we're doing now is trying to have a standardized operational planning framework and a standardized set of budgeting framework rules that apply to everybody, so that we can actually sit down as an executive committee, or as a senior management board, which is a subset of the most senior executives in the department, and ask ourselves on a regular basis: how are our priorities shifting, do we have the resources in the right place, and do we have the mechanisms in place to get more resources where we need them?

Frankly, the first thing you do...if I were to go downtown to the Department of Finance in the first instance, or the Treasury Board, and ask for help, they would say, we help those who help themselves, so have you looked inside your department? Are you sure that you're allocating your resources to your highest priorities? Should you be doing reallocation?

These are not easy things to do. It's easy to talk about reallocation. It's actually a very hard thing to do. There are some real entrenched interests inside and outside departments. So we need to work through that. And the best way to work through that is to make sure all the people on my team are pulling in the same direction, that they are not just preaching for their parish but are looking at the overall interests of the Canadian public in better health protection.

So these are the kinds of things we're doing. Frankly, what we're doing and putting into place now with an operational planning framework I think will make a big difference. Will it make it perfect? No, it will not make it perfect.

We had our first year under a department-wide operational planning framework this year. One of the things we did that I think was very helpful is that our chief financial officer branch called everybody together and said, having gone through this one year, let's do a post-mortem; let's do a lessons learned and start to apply that to what we're going to be doing next year. This is an interactive process. This is a learning process, and we are learning. I would say if we get better and better every year...and we can't afford to tarry; there's no question about that, given the interests at stake. But I think we're making progress.

#### • (1605)

**Mr. David Sweet:** My good colleague Mr. Williams constantly reminds us that we're a committee of accountability not management. But I'm going to have to take a risk and climb into management here a bit. I hope you'll forgive me, Mr. Williams.

But I am concerned about the fees for cost recovery that you charge industry. They haven't been reviewed since 1990. And I can't imagine how much revenue is lost that the taxpayers had to make up for now because these have never been reviewed. I hope that in these analyses you're doing you're looking at a regularized review of these, so that as new products come on stream, and those kind of things, you'll be able to have these fees updated on a regular basis.

**Mr. Morris Rosenberg:** Mr. Chair, perhaps I could ask my colleague Mr. Yeates to answer that since it's his area that is most affected by the fee structure.

#### Mr. Neil Yeates (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Thank you, Chair.

Yes, I can update you on that.

We are working very hard on getting prepared to begin the consultation process on a new cost recovery regime. You're quite right, they were set in 1993-94 or so, and they're significantly out of date. There are two respects: the impact of inflation on our current fee regime plus the regulatory regime continuing to develop over time. We need to think about areas where we're not currently charging fees.

As members know, this needs to take place under the auspices of the User Fees Act. It will have a very strong consultation process, and it will come back through Parliament.

It's interesting to note that for health products and food, the proportion of our budget from fees is around 25%. We're actually on the low end internationally. FDA is closer to 50%, the European Union is closer to 75%, and the Australians are at 100% fee recovery.

We think there is some room for us to grow there, but at the end of the day Parliament will decide.

Mr. David Sweet: Thank you.

Thank you, Mr. Chair.

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

Mr. Christopherson, eight minutes.

Mr. David Christopherson (Hamilton Centre, NDP): Thank you very much, Chair.

Thank you all very much.

I want to pick up where Mr. Sweet opened up, which is how we got here. I understand we don't want to spend too much time focusing on that, because that's not the real issue. But it is troubling.

If you look at the fourth paragraph of the Auditor General's statement this morning—I think this captures it nicely—the second sentence of that paragraph says: "Program managers have indicated to branch management that some core compliance and enforcement activities are insufficient to protect the health and safety of Canadians." To the best of my knowledge, every government that has ever assumed power in Canada recognizes its first and top priority to be the protection of the safety and health of its citizens.

I'd like to know who these program managers reported to. Who received information that there was inadequate review going on to protect the safety and health of Canadians and made a management decision not to push it higher? At what point did the actions stop, and who is accountable?

• (1610)

**Mr. Morris Rosenberg:** I take it that one of the methodologies used in the audit was interviews with program managers. I think the Auditor General, at an appearance before the Standing Committee on Health, had some comment on this.

My sense is this. Program managers talk to senior managers within their branches. The question is whether the view of the program manager that there are inadequate resources is dispositive—that it's the final word on the issue. In other words, because a program manager says so, does it mean it's so?

I think the Auditor General pointed out that there's a tendency all over government, not just in regulatory programs, that if you ask a program manager whether they have enough resources, they might say, well, I could always use more resources. So I don't know. I think that's part of the Auditor General's point, that we should know better and that we need better information and planning systems to be able to assess this.

You can get into a debate, for example, on regulation. Let me give you a current example that we're grappling with now. There is a task force on trans fats. You can regulate trans fats, and it's a very legitimate thing to look at. I think it's something the government would consider: command and control regulations. The inspectors go in, and if they find a violation, they prosecute. But it's a very expensive way to do business. The government will make a decision as to what the best thing is. But there are different ways of looking at this. A program manager may say, "I think I should be in there with all guns blazing", so to speak. There may be other ways of looking at a problem. Education is a cheaper way of looking at a problem, and it may be fully effective in dealing with the regulatory problem at issue.

**Mr. David Christopherson:** I hear you, and I accept that, but I have to say that it's not much of an answer. I mean, really, what it suggests is that reports and concerns were going in, and they were either deemed to be not credible enough to act on or somebody still didn't act on information when they should have. At the end of the day, the Auditor General went in and found out that there wasn't proper compliance. There's some reporting going on. Somebody said, "We don't need to do anything", and that's wrong. That's all I'm pointing out.

I want to ask about the chart on page 10 of the Auditor General's report, which points out the activities that are insufficient, and it is almost all of them. I'm wondering about products that are already out there now. I hear you have an action plan. I'm assuming we'll see that at some point, but I'd like to know about products that are out there now.

For instance, if I were thinking of conducting investigations of clinical trials, if there was insufficient activity being done to protect Canadians on that, it would mean there was a possibility that some drug products out there perhaps shouldn't be.

Could I have your thoughts on that, sir?

**Mr. Morris Rosenberg:** Mr. Chair, I would defer to Mr. Yeates, who has more detailed knowledge on this than I do, if that's okay.

#### Mr. Neil Yeates: Thank you.

Since the audit was done for these years in question, there have been two tranches of investment in the health product and the food regulatory regime. One was in 2003, and it focused on improving product review times. Canada had fallen way behind international standards on realistic review times for new products. So there was an investment made in 2003.

In 2005 a second series of investments dealing with drug safety issues was made. As the deputy's mentioned, that was post-Vioxx. The concerns at that time were inspections, safety monitoring, and so on. So in fact there was considerable discussion within the department on the kinds of things we needed to move forward on in those two years. There were new investments that came forward that are actually multi-year in nature, so that funding for these areas increased this year, and it will increase again in 2007-08.

#### • (1615)

**Mr. David Christopherson:** Maybe the answer's in there and I just didn't hear it, but the question was whether there were possibly products that have gotten through because there were inadequate clinical trials. Are there drugs out there that we're going to find out a couple of years from now are problematic, because the department

wasn't doing the kind of clinical trials that it should have been doing? That's what I'm asking.

Mr. Neil Yeates: Thank you for that clarification.

The reason I referred to the investment in performance review times is that we had developed a backlog in product reviews. The bottom line for us is that we never allow a product on the market without doing a thorough review. That's why a backlog was created. That's why the investment was made—so we had more capacity and stronger management systems to oversee this review process. So whenever we approve a product, we are confident that it meets the tests of the Food and Drugs Act for safety, efficacy, and quality, absolutely.

**Mr. David Christopherson:** Okay. And you don't feel at any time that you're being unduly pressured by industry, who are constantly beating the drum that it takes them too long to get things through? You don't feel there's pressure there for you to deliver and maybe move a little more quickly than you should?

Mr. Neil Yeates: Absolutely not.

**Mr. David Christopherson:** Okay, that's what I wanted to hear. I was hoping to hear that.

I want to ask about reallocation, as I have time. I did ask about the action plan. I gather, Deputy, that will be on its way?

**Mr. Morris Rosenberg:** We will be providing an action plan to the committee before the end of the month.

# Mr. David Christopherson: Okay.

And regarding reallocations, I just want to hear that you concentrated on that, and that there won't be any further diversion of money, especially to core programs. The Auditor General pointed out that she saw real problems with the way that was happening: it wasn't documented; it may or may not have been the right decision. Just give me some assurance, Deputy, that you're on that in a big way.

**Mr. Morris Rosenberg:** I can assure you that we are on that in a big way and in a number of ways.

First of all, with respect to the issue of documentation, it was raised in the report. One of the things the new budgeting framework will deal with will be rules around the documentation of decisions, allocation and reallocation decisions, including cases where we might have decided to allocate to a certain area and understand what the consequences might be for other areas. So we are very live to that. Also, as part of the budgeting framework, we are going to be ensuring that our folks understand that they must adhere to the conditions of any special funding that is provided by the Treasury Board, and if there is an issue, we would expect that the department, in the first instance, would have discussion with the Treasury Board about that.

There are things that will arise in the course of the year. One of the dilemmas here, I guess, is trying to strike a balance between working within the rules, which we should always do, but also having enough flexibility to be able to actually react to real threats to the health and safety of Canadians. What we're trying to do in developing this framework—and I think this applies beyond Health Canada as well—is to have the appropriate loose-tight fit so that you can do both things, so that you're not pushed into a situation where you have to break the rules, but that you can actually put money where you need it when you need it.

We're working on all these things.

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

Mr. Wrzesnewskyj, for eight minutes.

**Mr. Borys Wrzesnewskyj:** Thank you, Mr. Chair, and thank you, Mr. Rosenberg.

In the Auditor General's conclusions, she wrote, "To have an effective resource allocation process, Health Canada needs to allocate funds based on plans, risks, and priorities; sources of funding and program costs; and program results." Yet in her opening statement, in paragraph 4, she concludes by saying, "At the present time, the Department does not know whether they are above or below the minimum level of activity required in the three programs", meaning the regulatory programs.

Then when I take a look at exhibit 8.4, the first column, "Protecting public from hazardous products and substances", under the heading "Consumer Product Safety", it indicates that there has been an insufficient level of activity; under "Cosmetics", insufficient level of activity; under "Workplace Hazardous Materials Information Systems", insufficient level of activity; under "Consumer and Clinical Radiation Protection", insufficient level of activity; and under "New Substances Assessment and Control", insufficient level of activity.

Boy, the average consumer, the average Canadian, if they saw this, would be very concerned. In most cases when we have reports come before us, we're concerned because tax dollars may be mismanaged, but in this particular case we're talking about the taxpayers' lives. I'm actually very glad that the Auditor General has red-flagged this situation for the government, because serious action needs to be taken on these files.

Cancer, in its various forms, is one of the leading killers of Canadians. Very specifically, in a lot of these categories of products that you have listed here, we have "insufficient level of activity". I would certainly hope that as you review this Auditor General's report, when you go to Treasury Board you'll note to the government that we need to move seriously, because this isn't just a matter of tax dollars being wasted, but lives. In fact, this past fall a number of MPs had their blood tested, and they virtually had a chemical cocktail in their blood. Besides just the pre-market and post-market analysis and regulatory work that you do, has your department ever looked at the idea of actually going out there and getting a handle on not just what Canadians across the country are potentially facing but what they actually have in their bodies, especially our schoolchildren, who would be most gravely affected by these chemical cocktails that we seem to have inside our bodies? Has Health Canada ever looked at that as part of its process? It doesn't seem to be mentioned anywhere in any of these recommendations.

• (1620)

**Mr. Morris Rosenberg:** Let me try to start, although I probably will ask my colleague Susan Fletcher to take some of it, especially the last part of your question.

We take exhibit 8.4 very seriously, but we also have to take it in its context. The title of exhibit 8.4 is "Examples of regulatory activities considered by Product Safety managers to be insufficient". I would say that in the context of the planning process that we are undertaking, one of the elements is that there are many sources for determining what the priorities are and what the instruments are that should be used to deal with those priorities. One of the most important sources has to be dialogue with the product safety program managers themselves, so that we ascertain if we are *ad idem*.

This isn't a question of putting stuff under the rug or anything, but there is a legitimate discussion that needs to take place on the level of resources and the assessment of risk. You can take a zero-risk approach to life. Unfortunately, that's not life. You're always managing risk, and Health Canada is in the business of managing risk. Are we doing it appropriately? We have to have this dialogue with our managers about that.

Assuming there are things on which we feel we need to do a better job, we then ask a second order of question about how we do that. Do we do it through the primary instrument that we have, say, with the Hazardous Products Act, which is to schedule things under the Hazardous Products Act and regulate them? Or are there other equally effective or even more effective things that we can do?

If we find out, for example, that we're hearing from some of our counterparts in other countries that, through inspections, we may start to see lead in children's toys, maybe the most effective thing to do is to call up the toy manufacturers or importers and say this is a problem and they really don't want to have this stuff in their products. Maybe we should be telling them that if they are importing this stuff, they should stop importing it. If they don't stop importing it, we may have to use our more heavy-handed instrument, but let's start with something lighter. We could put advisories out to consumers. There is a whole range of things we can do.

When you look at this, it is actually not just a two-dimensional axis. This actually has a number of dimensions to it that have to be looked at. I don't discount it; I take it very seriously. But that's the discussion we have to have with our program managers. **Mr. Borys Wrzesnewskyj:** Perhaps coming back to a question that I had, now that this has been red-flagged—we weren't aware of this—will you be approaching Treasury Board and requesting funding? You mentioned children and toys with lead in them. Why not actually do tests of the Canadian public, especially children across the country, to give us an indication of what potentially is out there? For instance, if the lead in the toys hadn't been flagged by another country, we would not be aware of it. Yet if we did testing of actual consumers, we might get the heads-up that there's something out there that we should be concerned about.

**Mr. Morris Rosenberg:** That really goes to the last part of your earlier question on whether or not we are engaged in that kind of testing. On that, could I defer to Susan Fletcher, who can give you some information on that?

**Mr. Borys Wrzesnewskyj:** And please respond on Treasury Board and whether you'll be putting proposals forward.

Ms. Susan Fletcher: Thank you, Mr. Chair.

Yes, indeed, under the chemicals management plan that was just announced, there will be regular biomonitoring of a survey of Canadians. StatsCan will be doing it for us, and the first tranche of the survey is going to start this summer. We will know what chemicals are in people and in what quantities, and we'll be able to compare across the country. We will therefore be able to start thinking back about questions like, if this is what's there, how did it get into their bodies? We can then start looking to where the modalities or the vehicles will be for that. So that should help us a lot.

What we have to do with the Hazardous Products Act right now and what you see reflected in this table—is react to the whole variety of products that are currently on the market and try to identify which ones may be problematic. From there, we have to do the studies and take them off if necessary. As my deputy just said, because you can get things off quicker and it's to the benefit of Canadians, our interest is to work with manufacturers rather than having to use the heavy hand of a regulation, which is lengthy and costly.

The Chair: Thank you, Ms. Fletcher.

Thank you very much, Mr. Wrzesnewskyj.

Mr. Fitzpatrick, for eight minutes.

**Mr. Brian Fitzpatrick (Prince Albert, CPC):** I want to commend you, Madam Fletcher. You're way ahead of the curve here. You're ahead of the members on the public accounts committee as far as proceeding with good policy is concerned.

On the words "command and control" and not going there, that's music to my ears, because we live in a free society. I happen to like chocolate bars even though I know they're not very good for us. We can bring in a command and control society, but I'm not exactly sure it would be compatible with a free society. Sometimes we do things that aren't always good for our health, and you can probably notice that by looking at my anatomy.

Voices: Oh, oh!

Mr. Brian Fitzpatrick: I made it to 61 anyway.

I want to approach the area of prescription drugs. This is probably an area where I don't know nearly as much as I should know, but I assume that what Health Canada does on prescription drugs is work with health care professionals in the industry and with patients to provide guidelines. If there are risks involved in using prescription drugs, that knowledge is brought to the attention of people who are using prescription drugs. Is that a correct assumption?

**Mr. Morris Rosenberg:** I'll just say a word, and then I'm going to ask Mr. Yeates to comment, because it's his area.

Drugs are subject to a pre-approval process. We do an assessment of them. We share information with other regulators around the world as well. We don't allow drugs onto the market that we're not comfortable with. We allow them with conditions that we think may be appropriate.

Can I ask Mr. Yeates to respond?

• (1630)

Mr. Neil Yeates: Thank you, Chair.

Yes, that's essentially correct. We have the pre-market review process. We approve conditions for products. If we're not satisfied that the benefits outweigh the risks, we will not approve them. We approve product labels that have indications for use, and so on. That's what goes to physicians and so on across the country.

**Mr. Brian Fitzpatrick:** This question is leading to another question. Mr. Rosenberg mentioned the Merck product Vioxx and the arthritis issue. I know of a person who is involved in this on the Canadian side of the border. The information being provided to me is that the information provided by doctors and health care professionals in the U.S. on the risk of using this drug was greater. There was greater knowledge, greater information about the risk of using that drug, than there was on the Canadian side.

Is there any substance to that point of view? I know the lawyers are busy with their lawsuits on this matter, but his information is that he wasn't aware of the risk. If he had been on the American side, he would have been aware of the risk because their information was more comprehensive.

Mr. Morris Rosenberg: Maybe I could start on this.

I can't comment specifically on that because I'm not aware, but I do know the way these things work. Canada moved at just about at the same time as the U.S. Whether the information came from that side of the border or from Europe I'm not sure, but when the red flag went up on those products, I think pretty well all drug regulators would have moved at around the same time to take them off the market.

**Mr. Brian Fitzpatrick:** It isn't about it being off the market. It's about the information the patient and the doctor had when they prescribed the drug. That seemed to be their issue. The person had a heart attack, so that was his concern. His doctor and the prescription he had didn't have the same information as would have been available if he'd lived in Detroit. If there's substance to that, I'd be somewhat concerned as a Canadian.

It brings me, really, to a third area. We're 2% of the world's population and probably 2% of the world's economy. The EU and American economies and the Japanese economy are much larger than the Canadian economy. I'm sure they have agencies similar to Health Canada that deal with things like prescription drugs, and the amount they can allocate in resources in this area is gigantic compared to what a country like Canada can allocate.

My point is that I'd like to think that in this world we live in today we are sharing information, that it's seamless, that we're not trying to reinvent the wheel, and that we're not putting up barriers between other countries and ours. On the American system, we could say that maybe it doesn't go the extra mile on protecting public health, but I have extreme doubts about that. Any industry player in the United States knows darn well that if they don't go the extra mile in the American system, the American trial lawyers and the American tort system will put them out of business, so they have a strong incentive to make sure that full information is being provided to the public.

Do we have a lot of regulatory and statutory impediments to sharing information and establishing a seamless network with these other countries?

**Mr. Morris Rosenberg:** Mr. Chair, I think I'd like to ask Mr. Yeates to respond to that.

Mr. Neil Yeates: Thank you, Mr. Chair.

The member has hit upon a very important issue in terms of the future of food and drug regulation around the world. As you know, Vioxx was a global issue, and the action that was taken was global. We work closely with the FDA, in particular; one of our closest working relationships is with the Americans. But we also work closely with the Europeans.

We feel that we need to advance in something similar to the kind of system you describe. The term we use is work sharing. So we, as a regulatory agency, could do some of the work, the FDA could do another part, and the Europeans could do another part; we could split up the work, because all regulators around the world are having difficulty keeping up with the volume and the complexity of products coming through the front door. That's where we'd like to go. It would be very important, though, that each country retain the right to make its own final regulatory decision. Different countries have different tolerances for risk, for different cultural and historical reasons. So we feel a lot of the science work can be done in common, but countries will want to protect the right to make their own final regulatory decision.

# • (1635)

**Mr. Brian Fitzpatrick:** I do believe we should use common sense in this area. A lot of people around here accept Al Gore as the definitive thing on climate change, almost as the final chapter on the issue. I think if there are good scientists in Europe or the United States who have spent a lot of money on a drug like Vioxx, for example, have studied it inside out and know the risk inside out, I'd hate to see us pay a whole bunch of money in Canada reinventing the wheel in this area. We should use the good scientific information that's available elsewhere and maybe allocate resources to other areas where we may be able to get more bang for our dollar.

That would be my point. I have no more questions.

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

That, members, concludes the first round. We're going to go now to the second round. There's one area I just want to pursue before we do that.

This is to you, Mr. Yeates, or to the deputy.

On the regime of user fees, you indicated, Mr. Yeates, that the fees haven't been adjusted in your particular directorate for quite some time now and that it's probably time that you adjust them for inflation and other factors. We have now the User Fees Act, which gives us a whole round of consultations and other requirements that have to be met. Is this going to help your directorate or is it going to hurt your directorate? Will it allow you to charge the full...? Because I think the intent of government is to charge the actual true cost of the work that's being done by the government.

Secondly, if you are allowed to increase the fees, is there a possibility that you may be raising expectations to a level that you don't have the resources to fulfill? I'm talking about timelines and that area.

**Mr. Neil Yeates:** Mr. Chair, our intent with the new cost recovery regime—as I said, we hope to begin consultations next month—is to bring additional resources into our regulatory system. So in that respect it's very important for us. The User Fees Act requires that we establish service standards for each of the fees that we propose. In some areas that's quite easy to do, and in others it's much more complicated. I'll give you two examples.

We do inspections of manufacturing sites. That's fairly easy to measure; it's a certain amount of activity. In an area like that, we think it's likely to do full cost recovery. In post-market surveil-lance—looking at adverse drug reaction reports, that kind of thing it's much more difficult to identify the receiver of the service. In many ways it's the Canadian public. So we're going to have to establish and propose what the right balance is in each area of our activity. I expect we'll end up with a mix of fees that really reflects the balance of public and private interest—100% in some, and much lower in others.

The Chair: Thank you very much.

I just have one additional question, and it goes to the auditor. This is a very important issue and I think it concerns most Canadians. Mr. Christopherson was right that the primary function of every government is to look after the security and the protection of its citizens. I haven't read the departmental reports or the report on plans and priorities of the Department of Health, for obvious reasons, but if I were to read them...would a parliamentary committee get a full grasp of the items that you've identified in your report? Would they be enumerated and elaborated upon in both those reports? **Ms. Sheila Fraser:** I believe, Mr. Chair, there is some mention of performance measurement within the departmental performance report. Again, as we say in this report, we think the department can do a better job of explaining its performance with measurable targets. There may be objectives that have been set, but they aren't always measurable targets. As we've been trying to stress throughout this, you need that baseline data about what activities should be carried out to be able to comment on whether you have achieved all the objectives of the program.

The Chair: Thank you very much.

Just before we go to the second round, I want to remind members that five minutes goes by very quickly, so keep your questions short and to the point. I urge witnesses to keep your answers brief and focused.

Ms. Sgro, you have five minutes.

Hon. Judy Sgro (York West, Lib.): Thank you. I don't tend to go on too long with preambles. I'm pretty short and to the point.

I've read the Auditor General's report, and you make it quite clear that for the program managers to follow their product sufficiently, there's insufficient funding there. Those things clearly are issues that will alert all of us when it comes to making sure that regulations and so on are followed through on in the enforcement activities and so on.

Is there a plan to point out some of these shortcomings in the budget, so that you ensure you've got adequate funding, or are you going to look at reallocation in your own budget process?

#### • (1640)

**Mr. Morris Rosenberg:** Mr. Chair, as I said earlier, one of the very first things we'll do as part of this internal departmental operational planning process is sit down with our program managers and make sure that we are *ad idem* on the diagnosis of the problem. Interviews were done with program managers for the purposes of this report. We take those very seriously. But we think we need to make sure there's a reconciliation of views and that we are talking about the same level of risk. We will do that, I assure you, as part of the ongoing work. We'll then make an assessment, and if there is a need for resources, we will first look internally at the possibility of reallocation.

Are there things we're doing that might be lower priority from which we could allocate money for issues that are a higher priority or a greater risk to the Canadian public? If the answer to that is yes, that may be the end of the story. If the answer to that is no, then we might go and speak to the Treasury Board or write a memorandum to cabinet to ask for more resources, as we did in 2003 and 2005.

**Hon. Judy Sgro:** Do you not have to go to Treasury Board normally on reallocation?

**Mr. Morris Rosenberg:** It depends on whether we're within the budgets that we have, so that we could reallocate within the same program activity, or whether we might need some authority from the Treasury Board to do that.

**Hon. Judy Sgro:** But the issue was pointed out in the audit, that there was reallocation with insufficient documentation?

**Mr. Morris Rosenberg:** Yes, and we have undertaken to provide sufficient documentation. We have also undertaken, under our new budgeting framework, to ensure that people understand the conditions under which money for special initiative programs was provided, and to respect those conditions. We recognize that we have a responsibility as well, within Health Canada, to engage with the central agencies to make sure that the planning and budgeting frameworks are robust and flexible enough to take into account the fact that there is a constant change in what's going on in the environment out there, and that we need to be able to react to that in order to fulfill our mandate to protect the health and safety of Canadians.

**Hon. Judy Sgro:** Numerous industries have complained about the costs they currently have to pay for getting the approval process through. But more importantly to them, and to Canadians, was the length of time it takes to get drug approvals through. And that's not full cost recovery. So I gather, under this, there's going to be a significant increase in the costs that the industry is going to pay to get that process through. But has there been any intent here to beef up the process so that it doesn't drag on for such a long period of time, given the fact that they're going to be asked for additional dollars to ensure that the funding process goes through?

**Mr. Morris Rosenberg:** First of all, in the therapeutic access strategy put in place in 2003, significant new funds were provided to the department in the budget of that year to specifically deal with the question of backlog. We have cleared the backlogs, and this is without having done anything on the fee side. In putting a new fee structure together, one of the things that we will do, and we are in fact required to do by the User Fees Act, is to develop a set of service standards that are commensurate with the level of fees that we'd be looking for. There would be consultations with the industry, and indeed with Parliament, on any proposal to increase fees, and then on what those service standards would be.

Hon. Judy Sgro: Okay. Thank you.

The Chair: Thank you, Ms. Sgro.

Mr. Sweet, you have five minutes.

**Mr. David Sweet:** Mr. Rosenberg, I've heard your answer on a couple of occasions. Basically you're saying, when members of the committee ask whether you'll go back to the Treasury Board for funds, that you're not convinced. It's not management's concern right now, and you need to make that investigation. Is that basically it?

**Mr. Morris Rosenberg:** Let's say we're not talking about cataclysmic events. We're not talking about Hurricane Katrina or something like that, when it's obvious that there isn't going to be sufficient money. You're talking about kind of normal risk.

# • (1645)

Mr. David Sweet: Day to day.

**Mr. Morris Rosenberg:** The first thing you would do in any program, I think, is ask yourself whether you have the flexibility within that program, within other programs in the same branch, and then within the same department to manage, before you go to the Treasury Board. Because if you didn't do that, the Treasury Board would send you back to look at your own—

Mr. David Sweet: That's sufficient for me.

Madam Fraser, do you feel comfortable and confident right now that this department is now on track with these recommendations and is beginning to move in the right direction expeditiously?

**Ms. Sheila Fraser:** Well, we've certainly seen, I think, a commitment on the part of departmental management to move in this area. They've indicated to us, in their operational planning exercise, that they're going to be putting it in. They've indicated, as well, that they will be establishing a list of activities, I think, by the end of 2008, the current year, which seems reasonable. These things cannot all be established overnight.

So yes, I think there's some indication of commitment there. Obviously every auditor will tell you that they'll hold judgment until they actually see it in place, so we may come back at some point in the future to do a follow-up, but—

Mr. David Sweet: At this point, all the positive indicators....

Ms. Sheila Fraser: —the responses are very positive, yes.

Mr. David Sweet: I have two more questions.

First, Mr. Rosenberg, just for our committee, can you make a statement today, in thorough confidence—because there are dates of 2007 and 2008 when you're going to comply with these recommendations—that you're on track with these responses to the recommendations and with the actions you're taking?

**Mr. Morris Rosenberg:** I can make a statement that we are on track and that we will monitor throughout, on a regular basis, the implementation of them. I think one of the benefits of an Auditor General's report is that it does tend to focus the mind. That's reality. So we will be monitoring on a regular basis our ability to comply with these management improvements we're putting in place.

If something were to change, we would talk to a number of people, including the Auditor General, about that. But right now, we're aiming for the dates we have and that you'll see in the action plan we put forward.

Mr. David Sweet: Right.

My last question is whether you can give the committee an overview of the relationship between Health Canada and the Public Health Agency.

**Mr. Morris Rosenberg:** Yes. You get into the concept of portfolio management. The Public Health Agency's origins, I guess, were around the SARS crisis and the report that was done that reflected that there ought to be a stand-alone agency to deal not only with infectious disease matters but with other public health matters, and that there should be a chief public health officer for Canada in charge of that agency.

The evolution is that this was a branch within Health Canada before that. It was the population and public health branch. So the chief public health officer, the head of that branch, is a deputy head, with all the authorities—financial, administrative, and so on—that I would have, and he reports directly to the Minister of Health.

Within the portfolio, there are a number of organizations, including the Canadian Institutes of Health Research, the Public Health Agency, us, the Hazardous Materials Information Review Commission, and the Patented Medicine Prices Review Board. That's the portfolio. We try to do some portfolio coordination, such as coordination of policy and, where possible, some coordination of financial requests, because we tend to be looked at as a portfolio and as an envelope.

So there's a need for that. Health Canada will play a kind of leadership role, if you wish, within the portfolio, as first among equals or something like that. That might even be too strong a phrase. It's very collaborative. We don't want to be working at crosspurposes for the same minister, so there is coordination that takes place in that regard.

Mr. David Sweet: Thank you.

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

Madam Brunelle, cinq minutes.

[Translation]

Ms. Paule Brunelle (Trois-Rivières, BQ): Good afternoon, ladies and gentlemen.

I am somewhat disturbed by certain things that I read in your reports.

Mr. Rosenberg, you gave us a very good explanation of the responsibilities of Health Canada. I see that you are dealing with a range of files that involve drugs, medical equipment and other health products, food, pesticides, hazardous substances in the workplace, the quality of air and water, and so forth. This is enormous. It touches on every area of our lives. We know that there are old problems that still persist while new problems come up that involve environmental issues. Moreover, we are exposed to various viruses from abroad.

However, as Ms. Fraser said in her presentation, the audit showed that the core funding budgets had been substantially cut over the past three years. For instance, the Product Safety Program was cut by 10%, the Drug Products Program was cut by 32%, and the Medical Devices Program by 50%.

In addition, Ms. Fraser's report states the following:

8.22 The Product Safety Program has requested additional funding, but it received very little funds for special initiatives in 2005-06 to address the shortfalls presented above. Program managers indicated that their inability to carry out these responsibilities could have consequences for the health and safety of Canadians, such as exposure by consumers to non-compliant hazardous products. There is also a risk of liability to the Crown.

Please, reassure me. I am thinking of contaminated blood and of C. difficile and a tendency to imitate the United States by taking everything to court. I must confess that I am confused. The people concerned by this should have many questions to ask.

### • (1650)

**Mr. Morris Rosenberg:** I think that the report shows that even if the core funding was cut, the funding from all other sources has generally remained the same. On the other hand, the report raised the following question that we are dealing with in our departmental planning. We want to know whether a specific activity is sufficiently funded by budgets from all sources and if we are carrying out our responsibilities adequately. As I said, we are not starting from scratch. Every day, we carry out an entire range of activities to evaluate the risks that products can pose to Canadian consumers. That is what we are doing for hazardous products. Management is applying an entire range of methods like inspections, monitoring, following up on consumers' complaints, discussions with the regulatory authorities of other countries, to be really sure that we can carry out our mandate.

As I said and as we read in the Auditor General's report, the management framework could be improved in order to do this, and this is the objective that we are currently seeking to attain.

**Ms. Paule Brunelle:** Ms. Fraser, I see that the issue is becoming increasingly complicated. You suggested that we should ask Health Canada to give us an action plan with a specific schedule for implementation, etc. From what I hear, I think it would be useful.

In your opinion, what should this action plan contain?

**Ms. Sheila Fraser:** I suggest that the committee refer to our recommendations, with which the department has agreed. You need to see the specific measures that they intend to take in view of our recommendations, as well as who is responsible and what timetable they have. In some cases, resources will have to be allocated. In fact, activities like these studies need funding.

This is the kind of action that I would envisage. I gather that it will be ready for tabling with the committee by the end of this month.

**Ms. Paule Brunelle:** Mr. Rosenberg, what items would you choose to include in this action plan?

• (1655)

**Mr. Morris Rosenberg:** I would choose to improve operational planning and to provide a budget planning framework that would give our managers clear directives regarding the principles and rules to follow in determining priorities and carrying out audits, including documentation relative to decisions.

Ms. Paule Brunelle: Thank you.

[English]

The Chair: Thank you very much, *merci beaucoup*, Madame Brunelle.

Mr. Christopherson.

**Mr. David Christopherson:** Are you sure it is not the Conservatives' rotation?

The Chair: You're more important than they are.

Mr. David Christopherson: I don't believe you without an audit.

First, at the end of the auditor's comments today, she suggested we may want to ask for a detailed action plan, which we've done and which you've committed to by the end of the month. Second, will a timetable for its implementation come along with the plan? Third, we asked for a progress report. I would ask you, Deputy, what would you consider a reasonable time for your first progress report, and what intervals do you think is a reasonable period for you to report back to us on how you're doing?

**Mr. Morris Rosenberg:** If we provide the action plan to you by the end of the month, then midway through this next fiscal year, which should be around September, would be a reasonable time, and then another one at the end of the year.

**Mr. David Christopherson:** Auditor General, does that sound reasonable from where you sit?

**Ms. Sheila Fraser:** That sounds reasonable. It would obviously depend on the deadlines the department has given itself. If it's within a year, then it should be six months and perhaps another six months after that, or something like that.

**Mr. David Christopherson:** We'll take that under advisement in our report writing.

By the way, I don't know about my colleagues, but my sense is that we're very similar. When it has to do with health, safety, kids, the obvious sorts of things, we get very prickly, and that is the right approach.

You've done an excellent job here today. One step out of line and we were going to be all over you, I can tell you that. But you and your team have done an excellent job of dealing with this in a very forthright way. I just hope the implementation plan and the progress report are as good as your words were here today. I will obviously give you the benefit of the doubt, but I want you to know it was very impressive today.

I would like to ask Ms. Cartwright about a discussion she had with Mr. Pat Martin on the health committee last Wednesday. He was asking about asbestos, and as you know, in the *Canada Gazette* dated November 11, there is reference to asbestos products in toys for children. I find it confusing because the statement is that "the presence of asbestos in consumer products poses a health risk that also needs to be addressed". Then you go on to provide a chart that says that asbestos is okay, and this is the wording: "A product that is used by a child in learning or play". Requirements: "Airborne asbestos cannot become separated from the product".

It sounds to me as if under certain conditions you're allowing asbestos in children's toys. Please explain.

Mrs. Susan Cartwright (Associate Deputy Minister, Department of Health): Mr. Chair, there is a confusion of the Susans here. It was actually Susan Fletcher who had the exchange with Mr. Martin. I'm sorry.

**Mr. David Christopherson:** I'm sorry. You're both on this page and you're both Susans. You're right, it is Ms. Fletcher.

Mrs. Susan Cartwright: Could I ask Ms. Fletcher to respond?

Ms. Susan Fletcher: Thank you very much, Mr. Chair.

There is some confusion around what was gazetted in November last year. We have a number of asbestos regulations, and what we gazetted last year was a refinement of all those regulations into one place, so that we didn't have them in a variety of places. There was no change through that gazetting in what we did in the way of protecting the health of Canadians. That being said, you are entirely right. When you read that chart, it does say.... And when we first put in the regulation on asbestos in children's products, the only science that existed showed that asbestos is only a problem if it can be inhaled. I asked the question because Mr. Martin asked me what happens if the child happens to eat it. There is no current science that suggests that eating asbestos is a problem.

• (1700)

**Mr. David Christopherson:** What if it breaks apart in playing? Have you ever seen a kid with a toy that lasts longer than an hour?

**Ms. Susan Fletcher:** The regulation says it cannot break apart, even in play, and become able to be inhaled.

Mr. David Christopherson: I don't have a lot of time.

**Ms. Susan Fletcher:** I do want to say that to the best of our knowledge there are no products on the market today that have asbestos in them.

**Mr. David Christopherson:** Do you test? That's what I want to get at. We found out there's a deficiency in testing, and I hear you say the science is okay as long as it's this way. Asbestos in toys makes everybody react. Adding it all up, I want to make sure this isn't one of those that got through that shouldn't have.

**Ms. Susan Fletcher:** Absolutely, and the deputy has spoken about our cyclical enforcement, especially in children's toys. We annually check against our regulation of children's toys to verify whether there are any that have come on the market that might be hazardous. Also, we will continually monitor the science, not only in Canada but worldwide. If any science comes along that will tell us there is evidence that there is a problem, you can count on it, we will be out there, first of all working with the manufacturers, but then regulating if necessary.

**Mr. David Christopherson:** I'd like to say that's okay, but the parent in me is having a problem letting go. I don't understand why we would even risk it. We know the lives of people who mine asbestos are in danger. There is the whole chain of providing it as we're now looking at energy. It's not just what you do, but what it takes to get there, and the amount of water, air, and energy it takes to process something. It's the same thing here. Would it not be safer, given all the things you say in here about keeping asbestos away, to have a regulation that said no asbestos, especially in a kids' product?

**Ms. Susan Fletcher:** As a parent I would agree with you. The issue for us is that the Hazardous Products Act only allows us to regulate a product off the market if we have good scientific evidence that shows there's a problem. We can't take it off as a precautionary measure; that's not allowed under the act. We have to make sure we are always watching, one, to make sure there are no products on the market that we think are problematic; and two, that there's no new science emerging that will tell us there's a problem where we didn't think there was hitherto.

**Mr. David Christopherson:** You talk about some that might be problematic. Again, I admit I'm coming from a very simplistic point of view, but it seems to me as soon as you see the word "asbestos" that should be a problem and you should be testing it. Is that the case? Do we test everything here in Canada that has asbestos in it that is geared to be sold to our children?

**Ms. Susan Fletcher:** No, we don't, but when a product comes to our attention that's for children and it has asbestos in it, we would test it. As I said, to our knowledge there's none on the market at this point in time.

**Mr. David Christopherson:** I'm going to come back again. Wouldn't it make sense to just say that in Canada you can't have that product in there, period?

**Ms. Susan Fletcher:** Unfortunately, the Hazardous Products Act, the way it's currently written, does not allow that.

Mr. David Christopherson: Right, but it could be changed.

**Ms. Susan Fletcher:** Certainly we are in the process at Health Canada of reviewing our legislative backdrop. The Hazardous Products Act is one of those that we're currently reviewing, and that is one of the things we would be looking at.

**Mr. David Christopherson:** It's very troubling. I have to tell you that it bothers me that in this day and age when there's asbestos, kids, and toys, under any condition, under any kind of legal framework or regulatory framework, that we would say yes, go ahead, the science seems to be okay. How many times have we found our scientists, based on their best professionalism, because of what they didn't know down the road, still wished they hadn't allowed something? I just don't know why we risk it. That's very troubling.

Thanks, Chair.

**The Chair:** I have a question for the Auditor General. The whole issue of baselines I think is very important here, and the absence of program baselines. We have a situation where funds are being allocated back and forth and there really isn't any baseline issue. Do you think baselines should be in all regulatory programs? I'd ask you to elaborate on that issue.

**Ms. Sheila Fraser:** My general reaction to that would be yes. It's hard to know if you are meeting your regulatory responsibilities if you haven't set baselines. If you haven't established the level of activity—which of course can vary over time, as risks change and situations change—if you haven't established the baseline, then how do you know if you're allocating enough resources to it or not, and how do you know if you're carrying out the level of activity you think is appropriate? So I would say yes.

• (1705)

The Chair: Thank you very much, Ms. Fraser.

We've concluded both rounds. I'm going to ask Ms. Fraser if she has any parting comments, and the same with you, Mr. Rosenberg.

**Ms. Sheila Fraser:** I would like to thank the committee for their interest in this report. As I mentioned earlier, we are encouraged by the reaction from the department, and we see that they're already starting to take steps on this.

Thank you.

**Mr. Morris Rosenberg:** I want to thank the committee for their interest as well. We will be back to you with an action plan by the end of the month.

**The Chair:** On behalf of the committee, I want to thank all the witnesses for their presentations and appearance here this afternoon. We will be writing a report in due course.

Before I adjourn, there are three things I want to raise. First, tomorrow morning at 10 o'clock there will not be a formal meeting of the public accounts committee, but all members of Parliament and all senators are invited to attend a presentation by the Auditor General of her February 2007 report. I think there are seven chapters. Then on Wednesday afternoon at 3:30 we are to appear at a regular meeting with the Auditor General to deal with that report and all chapters.

Finally, Mr. Wrzesnewskyj, I want to come back to you. I have received your motion with six names of RCMP officers. We have two or three already. That's fine, but perhaps you could just elaborate by tomorrow in writing as to the relevance and how you see it fitting in with our investigation. Then when we come back on Wednesday we can vote on your motion.

**Mr. Borys Wrzesnewskyj:** Thank you, Chair. My office has already provided a synopsis on each of the potential witnesses, which has been copied to all of the committee members. That should provide adequate background.

**The Chair:** Thank you for that, Mr. Wrzesnewskyj. Again, that's only in English, so you're going to have to get that translated quickly.

Mr. Borys Wrzesnewskyj: We will get that translated.

The Chair: We will not circulate it until it's done in French.

**Mr. John Williams:** Did Mr. Wrzesnewskyj say that the background information on these people has been circulated to our offices?

**Mr. Borys Wrzesnewskyj:** No. It's being circulated right now to the committee members present.

**The Chair:** We didn't give it to anyone because it's not in English and French.

We have the motion but not the synopses. We'll have the synopses translated, and they will be circulated tomorrow.

Mr. Laforest.

[Translation]

**Mr. Jean-Yves Laforest:** Mr. Chairman, I just want a few clarifications regarding your earlier statements. You said that at 10 o'clock tomorrow, the Auditor General will table her report. Is it 9 o'clock or 10 o'clock, because certain documents say that it is 9 o'clock. In addition, will this be done in camera as was the case when the November report was tabled?

[English]

**The Chair:** I believe—someone correct me if I'm wrong—the lockup starts at 9 o'clock, when people can get copies of the report and read them. The Auditor General is making her presentation at 10 o'clock. All members of Parliament and senators are invited to hear her presentation.

What time will it be tabled in the House, Mrs. Fraser?

Ms. Sheila Fraser: It will be at 2 o'clock.

**The Chair:** It will become public at that time. The staff have to remain locked up until 2 o'clock. Members of Parliament and senators can leave once they go to the hearing.

#### [Translation]

**Mr. Jean-Yves Laforest:** Do we know in what venue or room the in camera sitting will be held?

#### [English]

The Chair: It will be in room 237-C in Centre Block.

[Translation]

Mr. Jean-Yves Laforest: Very well, thank you.

[English]

The Chair: Thank you very much.

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

Also available on the Parliament of Canada Web Site at the following address: Aussi disponible sur le site Web du Parlement du Canada à l'adresse suivante : http://www.parl.gc.ca

The Speaker of the House hereby grants permission to reproduce this document, in whole or in part, for use in schools and for other purposes such as private study, research, criticism, review or newspaper summary. Any commercial or other use or reproduction of this publication requires the express prior written authorization of the Speaker of the House of Commons.

Le Président de la Chambre des communes accorde, par la présente, l'autorisation de reproduire la totalité ou une partie de ce document à des fins éducatives et à des fins d'étude privée, de recherche, de critique, de compte rendu ou en vue d'en préparer un résumé de journal. Toute reproduction de ce document à des fins commerciales ou autres nécessite l'obtention au préalable d'une autorisation écrite du Président.