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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (0845)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): I call the meeting to order.

Good morning, ladies and gentlemen. I want to welcome our guests.

Pursuant to Standing Order 108(2), we're doing a study of the role of government and industry in determining drug supply in Canada.

With us—

Ms. Libby Davies (Vancouver East, NDP): Madam Chair, I have a motion I'd like to move.

The Chair: Yes?

Ms. Libby Davies: I offer my excuses to the witnesses, but I want to make sure we deal with this motion. I raised it at the last meeting.

The Chair: We're having committee business at the end of the—

Ms. Libby Davies: Yes, I know, but I still would like to move the motion now to make sure that it gets done. I think we could look at the timing in camera—

The Chair: Go ahead, Mr. Strahl.

Mr. Mark Strahl (Chilliwack—Fraser Canyon, CPC): I'd like to speak to this.

Ms. Libby Davies: Madam Chair, I'd like to move that in relation to its study of the role of government and industry in determining drug supply in Canada, the committee report its findings to the House of Commons.

When we agreed to do this study, the motion did not spell out that we would report our findings. I assume that everybody would want to do that; otherwise, why would we be hearing all of the witnesses? However, just to be clear, we should report our findings to the House.

If this motion is approved, which I hope it will be when we deal with committee business, then we could discuss the timing. I know we have other things on the go, so we can look at the actual timing of when we would have that meeting.

The Chair: I understand the motion.

Go ahead, Mr. Strahl.

Mr. Mark Strahl: Yes, I agree that we should report on these meetings. I would just want the motion to reflect the fullness of the original motion, so I will move an amendment.

Here it reads, “that in relation to its study of the role of government and industry...”, etc. The actual motion was that the committee “examine the role of government and industry in determining drug supply in Canada, how the provinces and territories determine what drugs are required in their jurisdiction, how the industry responds to them, and the impact this has on stakeholders”.

I would certainly want all of that to be reflected in the motion when we consider the reporting on it.

The Chair: To be clear, what you're trying to say is that we'll have the complete motion as introduced by Ms. Davies, but your amendment covers....

Could you go over your amendment again, please?

Mr. Mark Strahl: Yes.

The Chair: Is this an addition to what is in her motion?

Mr. Mark Strahl: Right. It would be an addition to capture the original motion that we agreed upon when we launched this study.

The Chair: Go ahead, Ms. Davies.

Ms. Libby Davies: Just to be clear, that was my original motion. On the advice of the clerk, it was shortened to this.

I have no problem with that; if your amendment basically follows the wording of what the original decision was, there's no problem. That's what we want to report, our study and the testimony of our witnesses.

I would consider that a friendly amendment; I'm happy to include it. I did originally, actually, so it's no problem.

● (0850)

The Chair: This is very good. We'll vote on the amendment first and then the motion, and we can do that now.

Ms. Libby Davies: I'm willing to just incorporate it into the motion.

The Chair: You're willing to just incorporate it in the motion?

Ms. Libby Davies: Yes.

The Chair: That's great. That's wonderful cooperation. I'm very proud of you guys.

(Motion agreed to [see *Minutes of Proceedings*])

The Chair: Thank you, Ms. Davies and Mr. Strahl.

We're now going to go to panel one. In our panel we have the Canadian Agency for Drugs and Technologies in Health, represented by Dr. Brian O'Rourke, president and chief executive officer; we have Dr. Jeff Poston and Mr. Jeff Morrison from the Canadian Pharmacists Association; and we have, as an individual, Dr. Joel Lexchin, professor in the School of Health Policy and Management at York University.

We're going to begin with the Canadian Agency for Drugs and Technologies in Health. Dr. Brian O'Rourke, please go ahead.

Dr. Brian O'Rourke (President and Chief Executive Officer, Canadian Agency for Drugs and Technologies in Health): Thank you, Madam Chair.

[*Translation*]

Thank you for inviting me to appear before the committee.

[*English*]

CADTH is a not-for-profit corporation funded primarily by Health Canada and all the provinces and territories, with the exception of Quebec.

We are a health technology assessment agency. This means that we provide independent evidence-based assessments of the clinical effectiveness and cost-effectiveness of pharmaceuticals, diagnostics, and medical, dental, and surgical devices and procedures. We do not make the final decisions on what technologies will be funded by health ministries; however, our work informs technology-related decision-making.

[*Translation*]

The Canadian Agency for Drugs and Technologies in Health, CADTH, provides a range of services to support the effective management of pharmaceuticals and other health technologies in Canada.

[*English*]

The common drug review program supports coverage decisions by 18 of the 19 publicly funded drug plans in Canada. We do therapeutic class reviews on pharmaceuticals and conduct optimal use projects that encourage the appropriate prescribing and utilization of drugs and other health technologies.

CADTH's Rapid Response Service addresses urgent jurisdictional needs for information that informs policy and practice decisions about drug and non-drug technologies.

[*Translation*]

The agency also does large health technology assessments when warranted. For example, last year, we did a major review of robot-assisted surgery.

[*English*]

Finally, our horizon scanning products alert decision-makers to new and emerging health technologies that are likely to have an impact on the delivery of health care in Canada. As part of this service, CADTH also provides environmental scans of different health care issues, practices, processes, and protocols inside and outside of Canada.

That brings me to why the committee asked me to appear today. In March 2011 CADTH published an environmental scan on drug supply disruptions. The scope of this report is a bit beyond our normal mandate, as CADTH is not involved in pharmaceutical procurement or the drug supply chain. However, as the drug shortage issue was becoming more prominent, Health Canada asked us to provide them with some background information on this issue. The report we produced is publicly available on our website, and a copy of the report has been distributed to committee members. This document was referenced in the House of Commons on March 12 during the emergency debate on drug shortages.

[*Translation*]

I will now provide a brief overview of our findings on drug supply disruptions as presented in that report.

[*English*]

First, I want to be clear that CADTH's environmental scans are not comprehensive, systematic reviews. Typically they are very time sensitive, so the information is based on limited literature searches and personal communications. They are meant to be informative, but are intended to be considered along with other types of information.

Many factors can influence the occurrence and severity of drug shortages.

Shortages of the raw materials required to make drugs contribute to drug shortages and are believed to be particularly problematic when an active ingredient is obtained from a single raw material supplier.

Manufacturing issues may create or contribute to drug shortages; for example, quite often multiple products are produced on the same equipment, which means that an increase in production of one product will result in a delay in production of another. There can also be temporary or permanent discontinuation of products as manufacturers shift production or reallocate resources. There can be numerous other problems associated with production.

Business decisions by manufacturers can also lead to drug shortages. For example, company mergers can be a way to create internal efficiencies in response to economic downturns, patent expirations, or a lack of new products in the pipeline; however, when companies merge, less profitable product lines are often reduced or discontinued, and sometimes manufacturing facilities are closed. Mergers of companies with similar product lines can lead to product consolidation, possibly resulting in changing a multi-source product into a single-source product, and single-source products are the most vulnerable to shortages.

Another major factor is the reluctance by manufacturers to provide advance warning of potential disruptions. This can magnify the impact of a shortage.

Purchasing and distribution issues can also play a role in drug shortages. For example, the use of just-in-time inventory control practices that involve keeping minimal supplies of drugs in stock at all levels of the supply chain can result in an overall reduction of readily available drug inventories.

Strict enforcement of good manufacturing practices and other related regulations by drug regulatory bodies can also play a role in drug shortages.

● (0855)

[*Translation*]

Madam Chair, these are just some of the many factors that contribute to drug supply disruptions identified in CADTH's environmental scan.

[*English*]

The causes of drug shortages in Canada are believed to be multifactorial. It is difficult to determine the extent of drug shortages in Canada because manufacturers are not required to report disruptions in drug supply and because there is no single accountable Canadian organization that provides system-wide drug distribution oversight.

The current drug supply issues underscore the need for greater transparency in the system as well as for strategies at every level of the drug supply chain that help minimize disruptions to patient care.

Let me now briefly present a potential option for CADTH, should we be invited by the provinces and territories to play a role in managing future drug shortages.

CADTH is both a producer and a broker of evidence-based assessments of health technology. We are a credible and independent source of information. We have the skills and processes available to produce drug substitution advice, and we can broker such advice created by others. Because of our skills in searching, accessing, analyzing, and publishing evidence-based clinical information, we have an ability to be a central source of information relevant to a drug shortage.

The role that CADTH might be able to play could best be summarized as a clearinghouse of shortage information and relevant substitution advice, and perhaps to provide a link to currently available databases and information sources. Information from CADTH could be used to supplement local efforts and to support clinical decision-making at the patient-clinician interface.

We are currently exploring this potential role with our board of directors, with senior federal, provincial, and territorial officials, and with other stakeholders.

Madam Chair, thank you for allowing me to present to you today. I welcome any questions that you may have.

The Chair: Thank you very much for your presentation. It's very much appreciated.

Now we have Dr. Jeff Poston, from the Canadian Pharmacists Association.

Dr. Jeff Poston (Executive Director, Canadian Pharmacists Association): Thank you, Madam Chair, and thank you for the invitation to appear today.

The Canadian Pharmacists Association is the national association that represents individual pharmacists. Our members work in community, hospital, industry, and academia.

We are pleased that the committee has agreed to hold hearings into drug shortages. We suggested to the committee a year ago that such hearings be held and, in fact, the committee had scheduled hearings in March 2011, but the fall of the government and the subsequent election resulted in the cancellation of those hearings.

Although there's been a great deal of attention paid to drug shortages over the past months owing to the Sandoz situation, the fact is that drug shortages have been a serious problem for health practitioners and Canadians for at least two years.

CPhA identified the scope of this problem in a survey of our members that we conducted, and we released the report in December 2010. This work was prompted by reports that we'd been receiving as early as March 2010 about shortages. We've provided copies of this report for your information.

In the survey, you will note that 94% of pharmacists reported not being able to fill at least one prescription in the past week, with the average number of drugs in short supply being 10. At least half an hour per shift was being spent on drug shortages, although we heard reports of many hours per shift being spent addressing some significant problems. Most importantly, 70% of pharmacists reported their patients' health was adversely affected, and over 90% reported that patients had been significantly inconvenienced.

It's important to point out that dealing with shortages consumes a lot of pharmacist and physician time that should be available for direct patient care. It's only the diligent work by front-line health care professionals that's been able to limit the impact of shortages on the population.

Although it is difficult to say whether drug shortages have increased or decreased in scope or duration since that time, the fact remains that drug shortages are a source of serious concern for the Canadian health care system. The events related to the Sandoz shutdown are just the latest manifestation of what has been a major concern for some time.

As an association we've worked with government, industry, other pharmacy groups, and other health practitioners to look at responses and solutions to this problem. In the fall of 2010 we held meetings with industry groups, wholesalers, and other stakeholders to better understand the causes of the problem. That prompted us, later that year, to release our guide to addressing drug shortages to our members as one tool available for pharmacists to deal with shortages when they occur.

There are many aspects of the problem, including causes that we could discuss today—and Dr. O'Rourke has mentioned a number of the causes—but given the time constraints, I'd like to take a few moments to outline a number of the solutions and recommendations that we feel are needed to address not just the Sandoz-related shortages, but the full range of shortages that are plaguing our health care system.

First, we were pleased to see the House of Commons unanimously adopt a motion on March 14 that called for the development of a national strategy to address the long-term issue of drug shortages. We applaud parliamentarians for recognizing this need and would encourage the minister to take the lead on the development of a national strategy.

Second, in response to the Sandoz shutdown, we have welcomed Health Canada's efforts at sourcing alternative supplies and expediting approvals of equivalent or alternative drugs. However, this proactive approach to sourcing supply in the event of a shortage should not be restricted to drugs impacted by Sandoz. This is a role that we believe Health Canada could and should be playing at all times to proactively address shortages. This is the role that the Food and Drug Administration plays in the United States, and we would argue Health Canada could be doing the same.

We would also like to see an increase in effective collaboration between Health Canada and the FDA on drug regulatory aspects related to drug shortages.

Third, governments and large purchasing bodies need to be aware of the risks associated with tendering systems that result in sole-sourcing. Although it is true that sole-sourcing, which is often associated with bulk purchasing, can lead to lower prices, the fact is that when problems are encountered by that sole-source producer, shortages can and will be the result.

● (0900)

Sandoz, which supplies approximately 50% of Canada's injectable pharmaceuticals, is a perfect example.

We understand that HealthPRO announced before this committee last week that they have introduced a new policy whereby they will seek secondary suppliers for hospital drugs when alternative suppliers exist. This is a very welcome development, and one we would encourage other group purchasing organizations and provinces to adopt. However, we wish to point out that in many existing contractual agreements, clauses exist to impose a penalty in the face of failure to supply, yet it is our understanding that these clauses are seldom implemented.

Fourth, in order to ensure that health practitioners and the general public have the most up-to-date information possible, the Canadian Pharmacists Association established in March 2011 a stakeholder working group on drug shortages to develop a voluntary drug shortages reporting system.

Today I'm joined by my colleague Jeff Morrison, who's been the chair of that working group.

An initial version of that reporting system went live in November 2011. Information populating the system is being fed by member companies of Rx&D and the Canadian Generic Pharmaceutical Association. It was announced just last week that this information is now being collated on one centralized website, at www.drugshortages.ca.

The working group is now working on a more robust system that would, we hope, contain therapeutic alternative information and that would allow health practitioners to report directly into the system to validate a shortage. While the industry associations have committed $200,000 towards the establishment of this system, we need to put in place a sustainable funding model to ensure continuity of this reporting system.

Fifth, this is not just a Canadian problem. It is a global problem, and therefore requires global attention. Last fall we were successful in getting the council of the International Pharmaceutical Federation to issue a statement calling for global action on drug shortages.

We strongly recommend that the Minister of Health request that the World Health Organization and the Organisation for Economic Co-operation and Development add this issue to their agendas and immediately look into the global causes and solutions to drug shortages from an international perspective.

Lastly, we need a forum to bring together all stakeholders, particularly manufacturers and regulators, to identify the root causes of drug shortages, provide more information to the discussion, and then, more importantly, identify what solutions can be implemented to alleviate shortages. Reporting on shortages and dealing with them when they occur is all fine and good, but our goal should be nothing less than to prevent any shortage before it can interfere in the care of even one Canadian patient.

In closing, I would like to emphasize that is not only an access to care issue but also a patient safety issue. The uncertainty and inconvenience created through having to manage a lack of supply can result in patients receiving less than optimal treatment and increases the risk of error. Shortages also take up a lot of time on the part of pharmacists and other health care providers, time that would be better spent in treating and caring for our patients.

Thank you, Madam Chair. We'll be happy to take questions

● (0905)

The Chair: Thank you very much.

We'll now go to Dr. Joel Lexchin, professor in the school of health policy, as an individual.

Dr. Joel Lexchin (Professor, School of Health Policy and Management, York University, As an Individual): Thank you very much, Madam Chair, for the invitation to appear here.

I have a couple of roles. First of all, I work as an emergency physician in downtown Toronto, and secondly, I teach health policy at York University. Moreover, I've been studying pharmaceutical policy issues for about 30 years now.

With regard to the first role, just yesterday we were discussing drug shortages in the emergency department at the University Health Network. We've had to modify certain practices because of these shortages. I'm well aware of the impact that drug shortages can have on doctors' prescriptions and patient care, which is what we're all concerned about.

I think drug shortages have been on the horizon for a number of years now. We've certainly been aware of them in the emergency department for a few years. It should not come as any surprise that we're now in more of a crisis situation. All it took was a fire to create a crisis.

What we need is proactive planning to avoid any similar situation in the future. Merely approving other generic manufacturers that are able to produce drugs is not really proactive planning. We need to go beyond that, and in that context I have a number of suggestions.

I believe that Health Canada should convene an expert committee to identify off-patent drugs. Most of the products we're concerned about are generics, off-patent, that are supplied by only one or two companies. They are considered critical to medical care. Examples of these critical products might be chemotherapeutic agents, morphine, anesthetic agents, or drugs to treat epilepsy.

Once these critical drugs have been identified, Health Canada should proactively identify possible alternative sources of these products and determine whether the companies making them are prepared to supply Canada in the event of an emergency. Contingency contracts could then be negotiated with interested suppliers.

In the future, any company marketing one of these critical drugs in Canada should be required to give Health Canada a minimum of six months' notice before they stop supplying the product, and Health Canada should maintain a list of these drugs and post it publicly.

One of the conditions for granting a notice of compliance to sell one of these critical drugs in Canada should be a commitment by the company to guarantee the availability of the drug for a minimum of three years. We already go beyond what's required in the Food and Drugs Act when we approve drugs or give them a notice of compliance; we now invoke patent issues, so asking for a commitment to supply the drug doesn't really break any new ground.

Finally, if we do have another crisis similar to the one we have now, we need to avoid any possibility that companies can take advantage of the situation by charging a premium for their products. In that regard, I think the federal government should consider establishing a publicly owned generic drug company to manufacture some of these drugs to ensure that the drugs will not only be available, but will be available at a reasonable price.

Thank you very much for your attention, and I welcome the chance to answer any questions.

● (0910)

The Chair: Thank you.

Go ahead, Ms. Davies.

Ms. Libby Davies: Thank you, Madam Chair.

Thank you to the witnesses for being here today. You've really helped illuminate not only the problem but also what we need to do. I really appreciate that. I want to jump right in and focus on what we can do.

There's something in the pharmacists' report from December 2010 that you distributed that you didn't exactly say today, but it's very clear in your report, and I'd like to quote from it. On page 11, under "causes", you say:

> What is missing in the drug supply chain is any organization or party that holds accountability for the supply chain from a system-wide perspective. Neither government nor any third party has an oversight function for the drug distribution system, and therefore drug supply is dictated in large measure by the market.

You go on from there to spell that out a little more.

I think this is a very telling comment, because everybody is saying from varying perspectives that there is no oversight, no mechanism to do this. We're completely reliant or dependent on, or held captive to—however you want to put it—what's going on in the marketplace.

I would also comment that in the brief that was just presented by the Canadian Agency for Drug and Technologies in Health, you also point out that the drug shortages are often difficult. You mention the mergers and the reluctance to share details of the shortages, again for business case reasons.

There are two questions that I would like to get at and have you answer. First of all, Mr. O'Rourke, you suggested that your organization might be able to fulfill that function as an independent overseer of information and in looking for substitutes. I'd like you to spell out how you could take that on and how quickly. I'd like others to comment on whether or not that is feasible.

Dr. Lexchin, in your brief you speak about establishing a publicly owned company. I was very interested to read in your brief that in the mid-1980s there actually was such a publicly owned company, called Connaught Laboratories. I don't recall that myself, but I wonder if you can speak a little bit more about this. I think your recommendations are great. This additional one about having a publicly owned company to ensure that some of the essential medications are there and that we won't have to face these kinds of shortages is a very brilliant suggestion.

I'd like you to speak a little more on how Connaught Laboratories worked, if you have that information. I don't know what happened to it, why it went under, or whether it was just done out of business by the government. Then I'd like the others to address the question of what kind of independent agency we need to provide this oversight.

● (0915)

The Chair: Who would like to take that question?

Dr. Brian O'Rourke: Madam Chair, I can probably speak to part of that question. On having one single agency to provide that oversight from a purchasing perspective, that wouldn't be CADTH. We do not have the expertise in purchasing, and a lot of that purchasing aspect is done through the group purchasing organizations.

We think we might be able to play a role if and when we have future shortages. I have been a pharmacist for many years myself. We've faced shortages in drug supply ever since I've been a pharmacist, and we've dealt with them.

What we're dealing with now, however, are more frequent drug shortages. Making those preparations and having clinical information available to pharmacists, physicians, and patients is where we think we could play a role. We can be proactive in identifying, as Dr. Lexchin said, critical drugs for which there is perhaps only one supplier and for which some information needs to be available to clinicians. That's more the role we would play, versus having a role in the oversight of the procurement.

Dr. Jeff Poston: If I can add to that, I think it's a great question but a difficult one to find a solution for, because you have to look at some sort of partnership between the federal government and provincial governments to do so. Provincial governments make some effort to protect themselves, if you like, from the impact of shortages, with some generic drugs that have exception status on the formularies. When they're single-sourced, they may be allowed to be sold at higher prices. The provincial governments have a role.

I think the federal government also has an important role. Health Canada has been developing some of that. We've seen it as a result of the Sandoz shortage.

Historically we've had this issue of the supply chain falling through the cracks. It's not something that is strictly the federal government's responsibility or the provincial government's responsibility. People have been happy to allow the manufacturers or pharmacies to manage the supply chain.

We certainly need a lot of discussion to work out the structure of some oversight agency. I think gathering data and gathering information is the first step.

One thing we have to think about is that we spend a lot of time regulating and approving new drugs that come onto the market. Then the organization that Mr. O'Rourke is responsible for, the common drug review, decides what's going to get listed. As a result, we spend a lot of time looking at what comes onto the market.

One thing we've got to look at is what goes off the market. One problem we've seen with a lot of drugs that have gone into shortage —and Sandoz is a specific issue of manufacturing, and that is another issue—is that they're old drugs. They've been generic for some time. They're low-value often low-volume drugs, but they're still clinically important. I think we have to look at how to address some of these older drugs that have been around for some time and how to keep them on the market.

The Chair: Thank you, Dr. Poston.

We'll now go to Dr. Leitch.

Ms. Kellie Leitch (Simcoe—Grey, CPC): Thank you very much, everyone. I really appreciate your presentations.

My first question is for the Canadian Pharmacists Association. I apologize; I don't know if it's Dr. Poston or Mr. Poston.

Dr. Jeff Poston: I've got a Ph.D., so you can say Dr. Poston.

Ms. Kellie Leitch: I didn't know, so I didn't want to be rude.

One item that's come up again and again is the working group, which had been focused on making sure that some recommendations were made to the minister. Your organization put forward that you were supportive of the voluntary system. In fact, I have the letter here that you were a signatory to. It's greatly appreciated. You also commented on the websites and other things available that others could feed into, the fact that there was a central focal point already.

However, later, for whatever reason, you decided to go against your words as stated here and you stated something different; you said you wanted a mandatory system.

Why is there the difference in the media? What was the cause for concern, and what are your concerns with regard to the change?

● (0920)

Dr. Jeff Poston: I don't think we've ever actually advocated for a mandatory system, but Jeff has been chairman of that working group, so I'm going to let him respond.

Mr. Jeff Morrison (Director, Government Relations and Public Affairs, Canadian Pharmacists Association): Thank you very much for the question, and yes, we're aware of that letter. In fact, I wrote that letter.

We've been supportive of the voluntary system really from the get-go. In fact, we put together that working group. We brought together the organizations that are signatories to the letter, so we've been advocating—

Ms. Kellie Leitch: Why the criticism in the media, then?

Mr. Jeff Morrison: What we've been talking about in the media, in particular—and I think we're referring to the role of Health Canada—are the items Dr. Poston spoke about in his presentation, which is what role Health Canada and the federal government can play in responding to shortages, not with respect to the reporting system.

As I say, we've been leading this working group that has been working towards a very robust voluntary system. We're still not there, but what we do think, and what Dr. Poston articulated, is that Health Canada needs to take on the proactive role that it took with respect to Sandoz. As Dr. Poston mentioned, that's a role we think Health Canada should have been playing before Sandoz and, more importantly, a role they should be playing moving forward.

Ms. Kellie Leitch: Then why is your attitude different in public than it is here in this room? I think we all are in this together. We want to take care of patients. I'm sure pharmacists do just as much as clinicians do, but why the difference in your presentation to the media and your aggressive attitude on that when we're all trying to be in this together?

Dr. Jeff Poston: I don't think.... I think there's perhaps been one media interview in which, as Jeff Morrison has explained, we talked about the importance of Health Canada's role. I think if you look at our press release and media statements in general, we've been pretty consistent in supporting a voluntary reporting system, but also, I think, pointing out that it if you look at the potential agencies and organizations out there that can play a role in affecting the situation, then clearly Health Canada has an important leadership role.

Believe me, drug shortages are not created by any one group or any one agency, and they're definitely not going to be solved by any one group or agency. I think it is very much a case that we are all in this together.

Ms. Kellie Leitch: To go back to Mrs. Davies' question, Dr. Lexchin, you did comment in your note about Connaught Labs. I think the impression with Mrs. Davies is that it was a federal government entity. Do you want to give a little elaboration on that? I know what Connaught Labs is. I think you know what Connaught Labs is. Just so people are clear on where that entity came from....

Dr. Joel Lexchin: Okay. Connaught Labs—my history may be a little rusty—grew out of the University of Toronto after they discovered insulin, but it was taken over in the late 1970s, I think, by something called the Canada Development Corporation. It wasn't a federal department, but it was federally owned. I believe it operated something like Air Canada used to or CN used to when they were publicly owned.

At that point, in the early to mid-1980s, it was making insulin and vaccines. It subsequently was sold off to Sanofi Pasteur, so it no longer is a public company. In fact, it's been merged a few times.

Ms. Kellie Leitch: To be clear, Connaught Laboratories was actually generated because of Banting and Best. It was so that insulin could be commercialized. Its site is in northern Toronto so that it could prove that purpose. It was never a federal government entity, nor was it actually a provincial government entity; it was an entity of the University of Toronto.

Ms. Libby Davies: That's not what he just said.

Ms. Kellie Leitch: I can tell you, because I sat in Banting and Best's office and I know the history of it. It was not a federal government entity at any point in time, nor was it a provincial government entity. It was an entity of the University of Toronto—

Dr. Joel Lexchin: No—

Ms. Kellie Leitch: —which is a publicly owned institution—

Dr. Joel Lexchin: No; it was, in fact, owned by the Canada Development Corporation in the mid-1980s, but we can—

Ms. Kellie Leitch: It went from there to private ownership.

We can beg to differ on that. I'm happy to have the discussion about it, but it was generated by the University of Toronto. It was not a federal government entity, so....

● (0925)

The Chair: You still have two minutes, Dr. Leitch.

Ms. Kellie Leitch: Sure.

I wanted to ask you a little more, Dr. Lexchin, on one of the issues you brought up with regard to your recommendations.

My general impression is that you believe that it's the role—and I'm just asking for a specification on this—of the federal government to make the decisions with respect to pharmaceuticals and which hospitals receive them under what circumstances?

When I stand in the OR—and I mentioned this last week to those at the CMA—I don't pick up the phone and call the Minister of Health when I run out of a drug. I think you probably don't do that in the emergency department when you have a challenge. Could you outline your understanding of what happens when you have that shortage in your emergency department? Who do you go to in your institution to try to rectify that?

Dr. Joel Lexchin: Actually, we were discussing this yesterday at the pharmacy and therapeutics committee meeting of the University Health Network.

They try to plan in advance for what they know about shortages coming down the pipeline. If they have anything less than a one-month supply of product, they consider that there may be a potential shortage, so they go looking for alternative suppliers. If they can't find alternative suppliers, then we come up with a plan of what we can substitute for drugs that may be in short supply, or we ask departments in the hospital that are heavy users of those products to consider limiting them or switching to alternatives.

The Chair: Thank you, Dr. Lexchin.

Now we'll go to Dr. Fry.

Hon. Hedy Fry (Vancouver Centre, Lib.): Thank you very much, Madam Chair, and thank you all very much for coming today and expanding on this topic so that we can understand the many factors bearing on the situation we find ourselves in at the moment.

I was going to ask Dr. Lexchin about Connaught, but I think some of us are going to do some research on it and see. In fact, I think I remember that Connaught, if not government owned, was overseen by a public agency of the government at some time, in the same way, as you said, Air Canada was. I think there was a public component to it at some time.

This is something many people meeting with me have talked about. It's the concept, the idea, of looking at it. You cannot force a private company to make a drug. There's absolutely no way any government can do that. However, is there a way the government will have to belly up to the bar and look at finding a way to make sure that the absolutely necessary drugs for patient health and well-being are going to be accepted?

I just wanted to ask a couple of things. I'd like to go to Dr. Poston.

You've mentioned the U.S. Food and Drug Administration a couple of times. You mentioned that if we're looking at a global shortage, it might be worth our while—and I agree with you, actually—to start building blocks of people who can come and find solutions, either proactively or otherwise. The federal government and the U.S. Food and Drug Administration working together is a good idea.

Can you tell me, or can you flesh out for me, what exactly the U.S. Food and Drug Administration does to ensure that a shortage doesn't come and hit them between the eyes? How do they try to be proactive and prevent this from going on? I know that they take a very proactive role and I know that President Obama has actually pushed them to do even more. Can you just tell me what they do?

Dr. Jeff Poston: I'll start, and Jeff can perhaps add some stuff, because he met recently with the FDA.

There are a couple of things. For a number of years, the FDA had a position very similar to Health Canada's. They were not, historically, necessarily that proactive with respect to drug shortages. However, drug shortages have probably been a bigger issue in the United States than they've been in Canada, so there really was a need.

Like Health Canada, the FDA's responsibility was regulating drugs that came to market, but they took this additional role on in response to hospital pharmacists starting systems in the U.S. to address drug shortages and health care. They got the FDA involved in doing that. They have recently, as you said, as a consequence of a new executive order from the President, had more authority, and they have added some staff to do it.

Jeff, you might want to add to that.

Mr. Jeff Morrison: Yes. I had a great conversation with the acting director of compliance in the FDA, and I asked that exact question: "What do you do?" The FDA claims that in 2011 they alleviated roughly 190 to 195 shortages, so clearly they're doing something right.

What they said is that when they're alerted to a shortage—and they indicated that there's a high level of trust between manufacturers and the FDA—they essentially go through a four-step process.

Step one is to speak with domestic producers that have the capability to increase capacity for whatever drug is in short supply and to essentially request that they increase production.

Step two is to look at the drugs that are essentially in the approvals queue. They'll bring any drug that could be deemed an equivalent or an alternative to the drug in short supply to the top of the line; they'll expedite that particular drug.

Third, they'll talk to domestic producers that do not have the capacity to ramp up production and ask them if they could put that capacity in place.

Fourth, they'll look at foreign suppliers and issue the proper importation permits for foreign supply, again, of whatever drug.

They've indicated that as a result of this very proactive approach that they take, they've been able to alleviate roughly 190 shortages in 2011.

● (0930)

Hon. Hedy Fry: Thank you very much, Mr. Morrison.

Madam Chair, with your permission, I want to say that we have just researched this, Dr. Lexchin, and this is what we found: Connaught had grown under the university, but by the late 1960s, it became obvious that it was inappropriate for a university to own what had become a commercial enterprise. Because the federal government was concerned that this unique commercial concern should remain in Canadian hands, the Canada Development Corporation purchased it in 1972.

Do I have any more time, Madam Chair?

The Chair: You do. You have about a minute and a half.

Hon. Hedy Fry: Thank you very much.

I know that there is a misunderstanding about drug shortages. A lot of people think that they happen in the OR or the ICU and emergency rooms constantly, but we know, as you touched on a little bit, about simple drugs, old drugs such as Stemetil. It was one of the old drugs that was effective and that obviously is not cost-effective to make anymore.

This links to Dr. Lexchin's question. If it isn't cost-effective to make it anymore, but these drugs, many of them oral drugs, are absolutely necessary, is there anything one can do, short of going back to a Connaught model, to help make sure that those drugs are there?

Dr. Jeff Poston: I think you see provincial governments doing that to a certain extent. On provincial formularies there are a number of single-source generic drugs that get treated with what's called exemption status, or something like that. They're not necessarily subjected to the price regulation scheme that the province may have in place that determines listing on formularies, so there's a certain amount of discrimination in favour of a particular generic formulation.

I think what we see illustrating that as well is that just addressing the price of a particular drug in the marketplace isn't necessarily enough to prevent shortages, and that points to the multifactorial nature of the problem. The biggest issues are global. A manufacturing problem in one country you can perhaps fix, but if you have a global shortage of an active pharmaceutical ingredient, that's a major problem, because no one can make the product if for some reason the source of supply of the active pharmaceutical ingredient has failed.

It points to the need for activity in terms of market incentives and disincentives. We need action around regulatory issues—

The Chair: Thank you, Dr. Poston.

Mr. Strahl is next.

Mr. Mark Strahl: Thank you very much, Madam Chair. Thank you to the witnesses for providing us with your expertise this morning.

I wanted to discuss the actual motion that we're here to discuss, and I know we talked about it briefly at the beginning of the meeting. It is to examine "the role of government and industry in determining drug supply in Canada, how the provinces and territories determine what drugs are required in their jurisdiction, how the industry responds to them, and the impact this has on stakeholders."

I know we've certainly talked about the role of government and industry. I don't know that we've talked as much about how the provinces and territories determine what drugs are required and how the industry responds, etc.

We know that the provinces and territories are responsible for the management, organization, and delivery of health services for their residents and that they have the primary responsibility for health care delivery, including which drugs they buy and how they source them. That's what I want to talk about.

Mr. O'Rourke, you talked about strategies to minimize the impact on patients. Sorry, I'm paraphrasing there. What are your views on the sole-sourcing of contracts, and if provinces are going to sole-source the contract, what role do you think they have in ensuring that there is some sort of backup plan?

● (0935)

Dr. Brian O'Rourke: I think that's an extremely important concept. Sole-sourcing is probably one of the key factors associated with the Sandoz shortage, whether it was the provinces themselves or the group purchasing among all of the hospital groups across the country that led to it.

I will refer to one of the countries that we put in our report, New Zealand. It has a central agency in place for the management and purchasing of pharmaceuticals. They have some very strict penalties in place for companies that do not provide a critical product, or that run out of it.

I certainly believe that some backup plans need to be in place. It could be by identifying the critical agents that we really do need to have additional information or additional backups for, and/or some system whereby we can look at a more competitive market or for another source of that product.

Mr. Mark Strahl: In the testimony this morning, we also heard that in these contracts the provinces often have penalties for interruption of supply, but they're not enforced. Can you explain to me how that happens? Why would the province not exercise the contract, and why do they not go after the suppliers if they fail to supply the product?

Dr. Brian O'Rourke: I really wouldn't have an answer to that. I'm not involved with the purchasing.

Mr. Mark Strahl: It's very interesting to hear that. Hopefully through this committee, perhaps some provincial agencies will be compelled to respond to that.

I also wanted to talk about your indication that the generic drug market appears to face more shortages than the brand name market. Can you identify why you think that is? Also, what policy ramifications do you think that has as we consider the balance between generics and brand name pharmaceuticals? What does that tell us going forward, if there are more shortages on the generic side than the brand name side?

Dr. Brian O'Rourke: That is a tough question to have a simple answer to.

We have a complex market in Canada for pharmaceuticals, what with the provincial and federal responsibilities for regulation. The provinces and territories are responsible for the public drug plan, and there are commercial pharmacies as well as free-market pharmacies. To have one system that looks after the management of all of those key players would be very challenging.

Certainly some of the policies we've seen implemented over the last number of years regarding generic pricing have probably played a role. Some business decisions by manufacturers have come into play. They have at times wondered whether there was any value in continuing to make a certain product. There have been decisions from some of the brand name companies on whether they would make a product in a generic version. These decisions would probably be made globally, as opposed to in Canada, so it's all very challenging.

I think there probably are some balances we need to strike in our pricing policies as well as on the supply-and-demand side of it.

Mr. Mark Strahl: Are you aware of any provinces or purchasing groups that have indicated a willingness to cede their authority to the federal government to perform that role?

Dr. Brian O'Rourke: No.

Mr. Mark Strahl: Dr. Poston, the FDA system was referenced as perhaps being superior to our own. Certainly, it has done well in addressing shortages. Nevertheless, we also heard that President Obama felt compelled to give an executive order to do whatever it takes to provide necessary drugs. They also were experiencing a shortage.

Is the relationship between the FDA and the manufacturers voluntary, or are the companies mandated to provide all of that information? How regulated is that relationship?

● (0940)

Dr. Jeff Poston: I don't think it's regulated as such. Is it, Jeff?

Mr. Jeff Morrison: There are currently bills before the Senate and, I believe, the House that would mandate or regulate that relationship. At present it is primarily a voluntary relationship that's been built up over several years. With respect to the presidential order last year, it allowed the FDA to staff up. It increased the resources they had available to take on that proactive role.

The executive also issued investigative powers to the FDA to deal with the grey market and the price gouging that's been occurring in the U.S. as a result of this shortage. This is more a U.S. problem than a Canadian one.

The Chair: Madame Quach is next.

[*Translation*]

Ms. Anne Minh-Thu Quach (Beauharnois—Salaberry, NDP): Thank you, Madam Chair.

I would also like to thank the witnesses for being so informative.

My first question is for Dr. Lexchin. I am fascinated by your recommendation to establish a publicly owned corporation to manufacture critical generic drugs, a bit similar to what they do in Sweden.

Could you comment on the benefits of creating a government corporation to manufacture critical drugs to alleviate drug shortages?

[*English*]

The Chair: Who would like to take that?

Go ahead, Dr. Lexchin.

Dr. Joel Lexchin: I think you might have confused what I was recommending. I'm recommending that the monitoring should be a Health Canada function. The crown corporation would be charged with manufacturing some of these products.

It wouldn't guarantee continuous supply. If you have a shortage of active ingredients—and a lot of those ingredients come from China or India, where manufacturing quality may be a problem—supply would not be guaranteed, but it would mean that in the event of shortages, we might be able to control pricing on these products. The crown corporation wouldn't be in the same situation as a privately owned generic company, which makes decisions about which products to continue or discontinue based on economics.

[*Translation*]

Ms. Anne Minh-Thu Quach: Thank you.

Drugs have been described as products that are not necessarily the same as other consumer products, when it comes to ensuring patient safety and therapies.

Mr. Poston, when you spoke about the need for Health Canada to play a broader and more proactive role in these types of situations, you said you were in favour of a voluntary system for manufacturers to report conditions that pose a risk.

And yet, when manufacturers do not necessarily follow the rules and fail to report risks regarding their drugs, what do you think Health Canada should do?

[*English*]

Dr. Jeff Poston: One of the interesting issues we've had with drug shortages is this question of....

I think one of the challenges we all have is that the drug regulatory process and the exchange of information that goes on between the drug regulator and the manufacturer, whether it's FDA or Health Canada, is pretty much a black box. We really don't know what goes on in there.

One of the important issues around regulation of manufacture.... We've had two instances in the last two years in Canada involving manufacturing plants. One was in 2010, with the plant in Etobicoke, a generic manufacturer. To all intents and purposes Health Canada was comfortable with the manufacturing facility, as far as we know, but then we had the situation in which action was taken by FDA that resulted in shortages from both those plants.

The basis of our recommendation is that one of the things we'd like to see is much greater collaboration between Health Canada and FDA with respect to regulation and manufacturing.

● (0945)

[*Translation*]

Ms. Anne Minh-Thu Quach: I have one last question for Mr. O'Rourke.

At our last meeting, we heard from the Quebec society of pharmacists, the Ordre des pharmaciens du Québec. That organization told us that while the federal government does have the Special Access Programme, it has not been adapted to address the drug shortage.

Do you think Health Canada should adapt the federal government's Special Access Programme to drug shortages, which are not only more frequent, but also more severe, to maintain a stockpile of critical drugs for patients?

[*English*]

Dr. Brian O'Rourke: It would be very challenging for Health Canada to introduce that type of policy, which is very locally based, to determine the critical drugs that we require in our specific hospital and our specific situation. For many of the decisions it is very important to have the patient-physician interaction. You really need to understand the needs of the patients and of the individual institutions. To have that situated at the federal government would, I think, be a bit of a challenge.

The Chair: Thank you so much, Dr. O'Rourke.

We've come to the end of that round. I want to thank our guests for being here.

Generally speaking, I know everyone rushes to the back. I'm going to suspend for only one minute so that Health Canada can move into position.

If there are any conversations, please hold them outside the room so that we can continue our committee work. I would ask the committee members to stay in their places so that we can get started right away.

Thank you. We'll suspend for one minute, and then I want to welcome our guests.

From Health Canada we have Mr. Paul Glover, assistant deputy minister for health products and food; Ms. Barbara Sabourin, director general of therapeutic products directorate, health products and food; and Ms. Sharon Mullin, director of compliance, enforcement and coordination division.

Welcome. We look forward to your presentations.

I understand, Mr. Glover, that you will be giving the full 10-minute presentation. Thank you.

Would you like to begin?

Mr. Paul Glover (Assistant Deputy Minister, Health Products and Food Branch, Department of Health): Thank you, Madam Chair.

The Chair: Would committee members join us?

[*Translation*]

Mr. Paul Glover: Madam Chair, I am pleased to have this opportunity to update the committee on the progress that Health Canada has made in support of the ongoing national effort to manage the shortage of medically necessary drugs supplied by Sandoz Canada. I would like to begin with a brief explanation of Health Canada's role in the country's drug approval and supply system.

[*English*]

Health Canada's primary role is to ensure that drugs bought or sold in Canada, whether in shortage or not, are safe, effective, and of high quality.

Once Health Canada has authorized a drug, producers and purchasers are free to enter into commercial contracts for supply. Drug companies manufacture and supply needed medications; provinces and territories make the arrangements with suppliers to purchase them. Drug makers are the first to know when the production may be interrupted; provincial and territorial health authorities are the first to know the impact of a shortage on patients, and can plan accordingly if given enough time.

The term of supply contracts, the cost, the amount of production, the rate of usage, the number of suppliers required, distribution, and penalties for non-delivery are all worked out between the purchasers and the suppliers. Health Canada has no role or involvement in this regard.

When a shortage arises, Health Canada, consistent with its mandate and authority, works closely with purchasers and suppliers to ensure that any new supplies of needed drugs are safe, effective, and of high quality. Madam Chair, I'm pleased to report to the committee that we have made significant progress in this regard.

● (0950)

Health Canada is currently reviewing 35 drug submissions on an expedited basis. Of those 35, Health Canada has already approved 11. As of this morning, we have also approved 59 requests for emergency access to needed drugs through our special access program.

In order to ensure that the support we provide is of greatest use, Health Canada prioritizes drugs for review based on the needs identified by the provinces and territories. I want to assure the members of the committee that at no stage of our expedited review process has safety ever been compromised, nor will it be.

I must also caution members that an authorization does not mean immediate arrival of additional drugs in hospital pharmacies. Manufacturing capacity has to be ramped up, and safety and quality have to be confirmed at every step of the manufacturing process.

Hereto, Health Canada has provided prompt support. We have approved 10 sites additional to Sandoz's list of approved sites. These sites perform manufacturing and product testing for the Canadian market. Purchases and suppliers, including Sandoz Canada, are expediting the manufacturing and supply process.

Finally, purchasers must decide whether or not to buy, once a new supply has been authorized.

We have to be clear that it is unlikely that these new drugs will be in the Canadian supply system for some weeks yet. In the meantime, the focus of health professionals and of Sandoz will be on minimizing the impact of the shortage on patients. In this regard, it is important to note that the Public Health Agency of Canada has made available to the provinces and territories needed drugs from the limited stocks available in the national emergency stockpile system. To date, no requests have been received.

Madam Chair, in addition to expediting drug approvals, Health Canada is focused on encouraging better information-sharing between suppliers and purchasers. Through the various networks supported by the health portfolio, we are bringing purchasers and Sandoz together on a weekly basis to exchange the latest supply information and to foster national coordination in the shortage response.

As the committee will know, the Minister of Health has long made it a top priority to encourage companies to fill information gaps around actual and potential drug shortages. Doctors and pharmacists need enough advance notice of a shortage for treatment plans for patients to be smoothly adjusted if needed.

Health Canada's collaborative work with industry has begun to pay off. It has resulted in a commitment from Canada's research-based pharmaceutical companies and the Canadian Generic Pharmaceutical Association, of which Sandoz is a member, to communicate potential and actual drug shortage information to Canadians via two existing public websites.

Industry, together with the health professional associations, has also committed to the development of a national one-stop drug shortage monitoring and reporting system in 2012.

The impact of the Sandoz shortage has made it clear that getting this one-stop information site up and running is more important than ever. The minister was pleased to note that Rx&D and CGPA have recently come forward with a commitment to support funding for one national site.

The committee also heard a few minutes ago the desire of the Canadian Agency for Drugs and Technologies in Health to play a helpful role in drug shortages going forward.

Madam Chair, Health Canada supports making public reporting of potential or actual drug shortages a requirement. The minister was pleased to note that in the response to her letter seeking increased transparency around shortages, industry associations have clearly committed their members to public reporting of anticipated and actual shortages. In addition, reporting obligations can be made formally binding if purchasers of drugs on behalf of provincial and territorial clients embed this reporting obligation in their supply contracts, as well as a requirement that suppliers have contingency plans in place in the event that they are unable to fill orders.

Indeed, one of the main bulk purchasers, HealthPRO, told the committee this week that starting this fall it will be awarding multi-supplier contracts for hospital-specific items, and that when there is only one supplier, they will be actively pursuing other suppliers.

● (0955)

I would just like to reaffirm for the committee that Health Canada will continue to play its part on this important issue by approving alternate sources of supply during the Sandoz shortage, and we are working with our partners to find longer-term solutions that help cushion patients against possible future shortages.

[*Translation*]

That concludes my remarks, Madam chair.

I would like to thank the committee for inviting me to appear today to discuss a topic of paramount importance. I would now be happy to answer your questions.

[*English*]

Thank you.

The Chair: Thank you very much.

We will begin with seven minutes of questions and answers. I believe Dr. Sellah and Mr. Morin will share their time.

Who would like to start?

Mr. Morin, go ahead.

[*Translation*]

Mr. Dany Morin (Chicoutimi—Le Fjord, NDP): Thank you, Madam Chair.

My question is for Mr. Glover.

As you probably heard, Dr. Lexchin recommended that Health Canada create an expert committee to identify off-patent drugs that are supplied by only one or two companies and that are considered "critical" to medical care. I won't list all of his recommendations, which also call for Health Canada to identify alternative sources of drugs deemed critical to the health of Canadians.

I would like you to comment on his suggestion of convening an expert committee that would be tasked with identifying alternative drug sources.

Mr. Paul Glover: Thank you, Madam Chair.

[*English*]

First and foremost, to confirm for the member, I was not present during the previous panel, so I cannot comment directly on all of the interventions that they were able to make.

However, in response to the member's question, we do feel that it would be quite a challenge for Health Canada to play that particular role, as we do not know what is going on between the purchasers, the large bulk-purchasing agents, and the various suppliers. We would need to become party to all of those contractual arrangements. We do, however, think it's very important, and we encourage all jurisdictions to diversify their supply as we move forward.

Health Canada does take a look at all submissions provided to us from the drug companies, and we will provide alternate authorizations. In fact, in many instances we authorize numerous companies to provide the drugs available to the market. How we end up with a sole supplier of a particular drug....

In the current situation with Sandoz, of the eight drugs that the provinces identified as their highest priority, Health Canada had previously authorized alternate suppliers for all of those drugs, so it becomes a practice of purchasing that leads us to the sole-source supplier arrangements. We think that the best place for that intervention is between the suppliers and the purchasers. We've already seen that they're beginning to react and respond, based on their sole-source purchasing habits, and making the necessary adjustments.

The Chair: Dr. Sellah, I think we've used half the time now. Go ahead.

[*Translation*]

Mrs. Djaouida Sellah (Saint-Bruno—Saint-Hubert, NDP): I want to start by thanking the witnesses for their informative remarks.

What worries me, as a medical practitioner, is of course the drug shortage. I do not know what I would say to a patient who came to me and whose critical drug was out of stock.

According to the Canadian Agency for Drugs and Technologies in Health, new Health Canada requirements, such as the policy for notifiable changes, have contributed to drug shortages.

Could you describe the new notifiable change policy to the committee? Do you agree that new requirements by your department can contribute to drug shortages, and why?

● (1000)

Mr. Paul Glover: Thank you, Madam Chair.

[*English*]

At no time do we believe that Health Canada, through any of our policies or actions, contributed to a drug shortage. Through a matter of policy, there are always drugs in our queue waiting for approval. When we understand that a drug is medically necessary and is of priority to the health system, we can expedite the review process. That's something we do and have continued to do, whether drugs are in shortage or not. We give priority to new, innovative therapies, rather than approving a second or third me-too drug, if you will, and we continue to do that.

We have, through investments in the program, significantly improved our performance. We are meeting all of our performance targets, with the exception of generic drugs. In all instances, as we approve drugs, we do so with the full intent of making sure that they are brought to the market as quickly and efficiently as possible; that is, we provide authorizations that the drugs are safe and of high quality. It is really up to the market to determine, once the authorizations are provided, if they will choose to purchase from that source that we have authorized.

We are, in fact, aware of a number of instances in which, after we have authorized a product, the market has chosen not to purchase from that, or potentially the authorization holder has decided not to enter the Canadian market, despite having gone through our approval process and paying us substantial fees to achieve our approval.

It is difficult for me to say exactly why these drug shortages happen, since we do authorize numerous sources of supply.

Mr. Dany Morin: We still have one minute and a half, so I'm going to continue.

I'm going to follow up on my question that I asked you earlier. You said that you would prefer to let the suppliers and the providers arrange things among themselves and provide a solution. Health Canada does monitor the drug shortages that will come or that could happen down the road, right?

Mr. Paul Glover: Mr. Chair, we do not have a legislative or regulatory responsibility with respect to drug shortages. We continue to play a role when asked by provinces and jurisdictions.

If I may—I know your time is limited—we have the two public websites up and running right now. There are about 200 drugs that the pharmaceutical companies have posted on those websites that the health system is dealing with and that are in limited supply, so they're making alternate purchasing arrangements, they're changing their therapeutic approaches, and they have not asked for federal intervention. They're dealing with those at a very localized level—

Mr. Dany Morin: I don't want to cut you off, but I want to finish by saying that pretty much all the witnesses want Health Canada to be proactive in monitoring the current drug shortages.

The Chair: Thank you, Dr. Morin.

We'll now go to Dr. Carrie and Mr. Brown.

Who would like to begin? You're sharing your time, so I'll tell you when you are about halfway through.

Mr. Patrick Brown (Barrie, CPC): Thank you, Madam Chair.

I understand that our Minister of Health had been working aggressively behind the scenes to manage the transparency of drug shortages well before the situation at Sandoz arrived. I understand she's been in close touch with industry and has written several letters.

Could you enlighten this committee, in a chronological order, on what our Minister of Health has been doing on that front?

Mr. Paul Glover: Thank you, Madam Chair, for the member's question.

The Minister of Health did become quite concerned over a year ago about the global problem of the increasing number of shortages that were being experienced worldwide, not just in Canada but as a global problem.

She wrote to the various industry associations, including Rx&D in terms of the brand names, CGPA for the generics, the biotech industry, the Canadian Medical Association, the Pharmacists Association, the distributors, the wholesalers, and others. She asked them to work together, first to improve transparency, so that if there were drug shortages, there would be a way to notify the health systems so that they could respond, and second to take a look at what they could do in reducing the number of drug shortages that were occurring.

In response to her recommendation, a working group was formed. They began as a collective to address this issue. They wrote back to the minister with a plan that had three phases. The first phase, which is already up and operational, involves the existing websites, the ones that exist today, where industry is now posting drug shortage information and making that available to any and all Canadians in the health jurisdictions. There are two existing websites.

Our response was while that was a positive first step, it was not sufficient; there needed to be a one-stop site where all health system practitioners, professionals, provinces, and Canadians in general could go to get information on drug shortages. That's the second phase, which is being accelerated right now. The two main industry associations have put money on the table to build this second phase.

That will be a positive step. That new site should have increased functionality, and not just with regard to what drugs are in shortage. It will address the previous member's question with regard to how to deal with a shortage of a particular drug, what alternatives can be used to treat a patient, and other information that might help health system practitioners deal with shortages.

The other thing—

● (1005)

The Chair: You've got a few more minutes. In order to share time, we're going to have to be mindful of that.

Mr. Paul Glover: The minister also recently wrote to the associations to express her concern that their members weren't using the sites for reporting and were actually posting drug shortages on their own websites. The minister has since received written commitment from all the members of the industry associations that they will now begin using those websites and, in fact, we have seen a spike in the amount of reporting to the public websites accordingly.

Mr. Colin Carrie (Oshawa, CPC): Thank you. I'll be quick.

I wanted to ask you a question on jurisdiction. Most patients don't understand it, but we all have to operate within it—the professionals, the governments—regardless of how frustrating it can be at times. We actually invited the provinces to be here, but they declined to be in front of us. Even national organizations have been in front of us, and my colleague said that they're asking us to intervene. There does not seem to be an understanding that the federal government can't grab provincial jurisdiction from the provinces just because national organizations or opposition parties say we should be doing that.

Could you take a moment now and go over jurisdictions with this type of issue and define what the federal roles are, what the provincial roles are, and if you have time, how the professions that are actually on the ground can get that information up through the system?

Mr. Paul Glover: Thank you, Madam Chair.

Very briefly, the provinces are responsible for the delivery of health services. The federal role and the role that we play is in the approval of the drugs. Are they safe? Do they do what they say they do? Are they made with quality, so that every pill that a person takes is the same pill and has the same medication in it? That is our federal role.

The other thing that we do—not through my organization, but under the federal Patent Act, through the PMPRB, the Patented Medicine Prices Review Board—is monitor pricing. If there is a view that prices of some of the patent drugs are exorbitant, then they can come in and set a maximum. That is the federal role with respect to this area.

Provinces then deliver the health services. In addition, they create formularies for what drugs they will choose to pay for in their population for seniors, for people on social assistance, etc. They make decisions about what they do and don't want to list on their formularies. The only exception is if a drug is provided in a hospital setting, it is provided. If that same drug is provided outside a hospital, it would be a provincial decision as to whether it was part of their formulary or not. In a nutshell, those are the main roles and responsibilities.

The final piece is the colleges and the role that they play in training their health professionals to use these drugs. There is what we call “off-label use”. Health Canada will approve a drug based on what the company says is the indication that they're looking for, and we will put that information to prescribers on the label. However, the college then trains physicians who can say, “That's great; that's what the indication is for, but we would also like to use this drug for other indications.” That's called off-label use. It is completely legal and allowed, and it is within their jurisdiction as well.

● (1010)

Mr. Colin Carrie: Do I have any time?

The Chair: You have almost a minute.

Mr. Colin Carrie: In your speech and presentation, you said: In addition, reporting obligations can be made formally binding if drug purchasers, on behalf of provincial and territorial clients, embed this reporting obligation in their supply contracts, as well as a requirement that suppliers have contingency plans in place in the event they are unable to fill orders.

In other words, that's totally between two people or two organizations. They can put that in their contracts.

Are you aware if they do that, or does anybody do that today?

Mr. Paul Glover: Madam Chair, as we heard at committee, in Canada HealthPRO, one of the main large bulk purchasers, is introducing that very policy in their supply contracts. We think that's a very positive development.

We are aware that in other jurisdictions—again, not at the government level, but between the suppliers and purchasers—those contracts do contain those clauses, and they have been successful in helping to limit the number of drug shortages.

My main point would be that having that intervention as close as possible to the two parties that are able to adjudicate the problem seems to be the most effective.

The Chair: Thank you, Mr. Glover.

Dr. Fry is next.

Hon. Hedy Fry: Thank you very much for your presentation, Mr. Glover, Ms. Mullin, and Ms. Sabourin.

In countries that have dealt successfully with this drug shortage, such as New Zealand and the United States, they do a couple of important things: they identify the drugs that are going to be short, they anticipate, and they manage.

Now given that you, as a federal government, are responsible for regulation and approval, you have a huge role to play in identifying and managing and fast-forwarding areas where you think there's going to be a shortage and in other areas involving manufacturing the drugs, etc. There is a role.

We heard from many people who presented here that the Food and Drug Administration has been very successful in using their mandate to predict, identify, and manage shortages. First and foremost, patients need medication when they need medication. Many patients who don't get that medication could die or could be severely impaired for the rest of their lives.

When we start talking about whose jurisdiction is what, it becomes moot. It isn't really about who you pick up the phone and call; it is about whether the patient gets the drug and gets to be well. At the end of the day, I think the responsibility rests with the people who regulate the drugs and who are able to work with others—as I would like to say, a leader—to try to find a way around this problem. It's about human beings. It's about Canadians. It's about protecting them and caring for them.

We're trying to find a resolution here. It's not a case of fault or blame. Could we put that aside for a minute?

In November 2011 the Food and Drug Administration told Sandoz that they did not comply with manufacturing standards. Was your department aware of that in November 2011? Were you aware then of what that impact could be on real people? I hope you didn't know. If you had, I would have thought you would have felt it was a moral obligation to warn people that this was going to happen, so that doctors, anesthetists, pharmacists, hospitals, etc. could start stockpiling.

Were you aware of the November 2011 FDA ruling? If you were, did you tell people? Did you warn them? If you didn't, why not? That's my first question.

Second, I continue to hear the federal government saying that they are just regulators and approvers, but you're the fifth-largest deliverer of health care in this country, so you're not just regulators and approval parties. You actually deliver services to the armed forces, the Inuit, the first nations, etc., so you need to know how these people you deliver services to are going to be able to get their medications and be able to get help.

Can you give me an answer about your knowledge of Sandoz and about thinking a federal leadership role is required, first in delivering care to the people you need to and second in terms of coming together and working with the provinces to make sure Canadians get drugs?

● (1015)

Mr. Paul Glover: First and foremost, we agree that patients need to come first. We absolutely understand and respect that, and that's why we're doing our part in this time of crisis. We are not hiding behind our role, our jurisdiction, and we have taken extraordinary measures to expedite review processes to approve drugs through the special access program. However, as the member pointed out, all parties need to step up and do their part if we're going to be able to deal with these shortages. We continue to believe that we play a unique role, as do other parts of the health system, and we must all step up equally to respond to this challenge.

With respect to the November warning letter that was issued by the FDA, there are a couple of elements that are important for the committee to clearly understand. The FDA issued its warning letter. That was made publicly available. We saw it on the FDA's website in December. That was a warning letter. There was a deficiency, and it asked Sandoz to respond to that deficiency. It did not close the plant. It was not specific to Sandoz Boucherville; there are two sites in the U.S. It was a warning letter that did reference Sandoz but also included other sites in the United States.

It's also important to note that Health Canada had been in and inspected the Sandoz plant. As with the FDA, we had observations with respect to our inspection and had written to the company asking them to follow up with us as well. At no point were we aware that there would be a shortage, the crisis that we are facing today.

We followed up with Sandoz through the months of November, December, and January to understand how they would be responding to both our observations as a regulator in Canada and in regard to what they would be doing in response to the FDA. We were not fully aware of the full extent to which Sandoz would be dealing with this until they publicly wrote to all of their clients.

Hon. Hedy Fry: Excuse me, Mr. Glover. I just wanted to ask you if you have learned any lessons. Do you now think that the next time you see the FDA issuing a warning to anyone, you might think it could lead to this? Would you do what everyone is hoping the federal government would take leadership in, which is to identify, anticipate, and manage, as the FDA is currently doing, with regard to drug shortages?

I think this is what we're talking about here, taking some kind of responsibility. There was no legal obligation for you to notify anybody, but there was a moral obligation.

The Chair: Time is just about up if you want Mr. Glover to answer your question, Dr. Fry.

Go ahead, Mr. Glover.

Mr. Paul Glover: We are in regular contact, Madam Chair, with the FDA, and their approach is very similar to the Canadian approach. They require companies to notify them. When they are notified, they take steps similar to what we've been doing through this emergency, which is expediting review. They reach out to foreign jurisdictions; I personally wrote to the EMA, FDA, and other jurisdictions seeking alternate supply, etc.,

When shortages are brought to our attention, absolutely, we will continue to respond with the best interests of patients first and foremost in our mind.

The Chair: Thank you very much.

We'll now go to Ms. Block and Mr. Lizon.

Who would like to begin? You're sharing your time, so I'll let you know when you're about halfway.

Go ahead, Ms. Block.

Mrs. Kelly Block (Saskatoon—Rosetown—Biggar, CPC): Thank you very much, Madam Chair.

I would like to thank the representatives from Health Canada for joining us today. You mentioned that there was an earlier panel, and their presentations were very informative as well.

I want to go to a comment that you made, Mr. Glover, in your opening remarks. You said, “I would just like to reaffirm for the committee that Health Canada will continue to play its part”, and that was close to the end of your comments. We know that when there is a critical incident, such as the most recent drug shortage, it's important for everyone to understand what their role is, to play their part in addressing it in the short term, and then to work together to ensure that the issue is addressed in the long term.

In the previous panel, Mr. O'Rourke spoke of an expanded role for his organization as a sort of clearinghouse of information. In your opening remarks I believe you said you are aware of the expanded role that the Canadian Agency for Drugs and Technologies in Health is perhaps hoping to play when it comes to drug shortages. I'm just wondering if you would be willing to comment a little bit about what your understanding is around that role and what your thoughts are on it.

● (1020)

Mr. Paul Glover: Thank you for the question.

We've spent a lot of time today talking about the things we have done in response to this crisis, including the special access program and the expediting of reviews and approvals. They were in response to the crisis.

We would like to take action to help the entire system better manage, and in fact prevent, crises as we move forward, so we will continue to push very hard for that one-stop site and will require the drug companies to post the information to that site for the benefit of all. It would be for my agency so that we can do our part. It would be for the provinces and territories so that they can do their part in planning for these shortages and can mitigate them. It would be for bulk purchasers, who could look at their supply and what's happening and respond accordingly. Finally, it would be for local practitioners, so that they can be aware that if they have patients who need those medications, they may need to come up with alternative treatment plans and know what substitutes are available to them. That website will be critical, in the longer term, to being able to do those things.

While we're very pleased that the drug companies have come forward and have said that they're committed to that site, we frankly don't want the drug companies running that site. We think it's beneficial that the site be run by a neutral third party. We believe that a group like CADTH would be ideally positioned. We're in contact with the provinces and territories to explore feasibility and whether there's unanimous agreement that it would be the best place to house this kind of information clearinghouse.

That would also position CADTH to play a unique role in terms of the expertise it has in alternate therapies and in gathering best practices they're already aware of within the health system and distributing them to all the players.

We will continue to push for the requirement, as per the motion that was debated and passed in the House. We will push to make sure that we have this one-stop site up and available, not just for Health Canada—we have our role to play—but for all levels of the health care system, so that they can take the appropriate action to respond.

I know that this is a long answer. I apologize to the member.

Finally, we will continue to encourage and have dialogue with other jurisdictions about what's working in the attempt to adopt best practices. We firmly believe, as this committee has heard, in some of the practices in place in other jurisdictions, in particular those that have clauses in the supply arrangements that first and foremost diversify supply. Sole-source arrangements are dangerous. We've seen that in the past and we continue to believe that this is the case.

We understand that moving to diversify supply has an impact on price, so we'll continue to work with the provinces and territories to make sure that we have best practices for distribution, diversification of supply, pricing arrangements, and other things. We will offer any support and assistance we can to encourage them to do that.

The Chair: Go ahead, Mr. Lizon.

Mr. Wladyslaw Lizon (Mississauga East—Cooksville, CPC): Thank you very much, Madam Chair. Thank you, witnesses, for coming here this morning.

Madam Chair, on page 3 of Mr. Glover's presentation, it states that Health Canada approved 50 requests for emergency access to needed drugs through a special access program. I would ask if he can maybe share more information on how the special access program works and how this helps during a drug shortage.

I will ask my second question right now, and then if I have more time, maybe I will ask one short additional question.

During our meetings and in our study, we've heard a lot about the factors that contribute to drug shortages. Among them, single-sourcing is one of the main ones, I believe. Of course, there are recommendations related to the website and on whether it should be mandatory to identify drug shortages.

Even if you know about possible drug shortages, and you have that information, how do you apply it? What do you do in the situation? What recommendations would you have for bulk purchasers, provinces, and territories in situations that are beyond human control? There could be a natural disaster somewhere that disrupts production; these are beyond any mandatory reporting on possible drug shortages.

Can you address both questions, please?

● (1025)

Mr. Paul Glover: With respect to the first question, I'll turn to Barb Sabourin on the special access program.

However, I'll start by answering the second question. We believe, looking at and learning from all the lessons that we have been through, that information is critical in the event of any drug shortage. A particular drug may be in shortage and there will be alternate therapies available, which means that it's very simple for the health system to adjust. They may prefer drug X, but drug Y may be equally effective, and it's simply a matter of making the adjustments.

For some patients, drug Y may not work; the physician may have already tried it, and they'll have to look to other arrangements. It is definitely a practice of medicine issue that is case by case between the physicians and their patients, but guidance about what those alternatives are is first and foremost a health—

The Chair: I'm sorry, Mr. Glover, but we've gone over time. I'm sorry about that.

We're just about to the end. We have about three minutes.

Ms. Davies, do you want to take three minutes? We're going to suspend for a business meeting. Would you like to go into the second round?

Ms. Libby Davies: Don't we actually go to 10:30, so it looks like five minutes?

The Chair: Just ask your question, Ms. Davies. I need to suspend before 10:30.

Do you want to go into the business meeting, and I'll suspend after 10:30?

Ms. Libby Davies: No, but there is a big difference between three minutes and five minutes when time is tight. I can see the clock; we have actually five and a half minutes until 10:30. We go in camera maybe 30 seconds before that.

The Chair: Well, then, what we'll do is cut into the business meeting.

Ms. Libby Davies: First of all, Mr. Glover, thank you for being here today. I'm glad to hear that Health Canada is making it clear that you do support public reporting and that it be a requirement, as you noted in your brief today.

The huge issue that we're missing is the lack of any oversight. We hear a lot of information about different roles and who does what, whether it's provinces or the purchasers, but there has been a lack of oversight and leadership.

We had some suggestions today. It's unfortunate that you didn't hear the earlier presentations, but the one in particular that my colleague referred to was a suggestion that Health Canada should convene an expert committee to look at the off-patent drugs that are considered critical and are supplied by only one or two companies. Never mind if they are short or not; it would be just to have an inventory of the drugs that are very well used and are supplied by only one or two suppliers. Following that, possible alternative sources could be identified through Health Canada with this expert committee, so that other arrangements could be made if there were an emergency. That, to me, is very much based on public interest and public health interest, which is part of your mandate as well as that of PHAC.

I wonder if you could respond to that.

As well, we know that the Auditor General has said that Health Canada has been slow to approve alternate suppliers. This has also been part of the problem. I know that right now we're under an expedited process, but how long will that continue? I think the Auditor General did make that a very clear issue in terms of the approval process itself.

Mr. Paul Glover: Given we're very short on time, I'll be as brief as possible. I apologize if—

The Chair: I will, as I've told Ms. Davies, give you the latitude of time, so please answer her question fully.

Thank you.

Mr. Paul Glover: Thank you, Madam Chair.

With respect to the Auditor General, I would simply state that the audit was conducted prior to the update of new user fees. The challenge we faced when that audit was conducted was that the fees we charged were 14 years old. They were extremely out of date, and the organization was significantly underfunded.

On April 1 we introduced new fees that restore the balance. As a result of those new fees, we've been able to add a significant number of new staff to the organization. I'm very pleased to report to the committee that we are meeting performance targets on all areas except generics, and we are working quickly to get caught up in that one final area so that we can be meeting our performance targets. We've significantly improved as a result of the new fees that have allowed us to charge appropriately for our work; we're now appropriately resourced and have the staff.

● (1030)

Ms. Libby Davies: What about the generics? How long might it take to catch up with whatever backlog there is?

Mr. Paul Glover: We're working very diligently to determine how quickly.... We've undertaken a number of new processes. Unfortunately, I cannot give the committee an exact date today. We will be happy to follow up.

We're developing a work plan. We've hired new staff. We have to see how the training goes and how quickly they can get up to speed. We're also collaborating with foreign jurisdictions. If another jurisdiction has already approved a drug that is now in the queue for us, we collaborate with them. We want to see how those efforts work out so we can move through and get caught up as quickly as possible.

There is one thing about generics, and it was a deliberate decision. From a public health point of view, our priority was new, innovative therapies that are very important in treating new illnesses. Now we're catching up with generics. We have every intention of getting caught up, because we understand how important they are to the health system. We would be happy to table a more detailed plan with timelines on when we can do that.

On the issue of whether we should be overseeing where there's a sole source, we are happy to do our part. We will need to work with the provinces, and the provinces will need to work with the bulk purchasers. We license numerous suppliers. They are not responsible for telling us if they're supplying; we authorize the drug, give it a DIN, and give the company a notice of compliance. It then goes into the market.

In some instances there is competition among bulk purchasers for the best possible price. They don't collaborate and share that information. There would need to be a willingness from the health system to share with the provinces and with us whom they've chosen to supply which drugs so we could determine if there are sole sources for those drugs as we move forward.

Certainly if there's a willingness among all the jurisdictions to move forward—and we have a regular call with the provinces about that—we will be happy to do our part in that process.

Ms. Libby Davies: We will hope that will happen.

The Chair: Thank you so much, Mr. Glover, and thank you, Ms. Davies.

I want to thank our guests for coming and giving us this very insightful information. It's very good for us to have it.

We will suspend for one minute.

[*Proceedings continue in camera*]

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