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Chair

Mrs. Joy Smith

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● (1530)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good afternoon, ladies and gentlemen.

We are going to be going into another presentation today on Bill C-11. I want to thank the witnesses for coming today. It's very much appreciated.

We have witnesses appearing as individuals. We have Bruce Anderson, senior advisor, occupational and research safety; and Elaine Gibson, professor and associate director, Health Law Institute. Welcome.

We also have Roland Leitner, occupational health and safety consultant; and Raymond Tellier, medical microbiologist and associate professor. Welcome.

From our Public Health Agency of Canada, we have Dr. David Butler-Jones, the Chief Public Health Officer. Welcome, Dr. Jones.

We have Dr. Theresa Tam, director general, Centre for Emergency Preparedness and Response, infectious disease and emergency preparedness branch. Thank you for coming again, Dr. Tam.

And we have, of course, Jane Allain, general counsel for legal services.

As you know, we will ask for presentations from each party and then we'll go into our questions. We'll start with the individuals.

Could we start, please, with Elaine Gibson.

Ms. Elaine Gibson (Professor and Associate Director, Health Law Institute, As an Individual): Thank you. I have read through the testimony of other witnesses on this bill and I see three themes in particular emerging. First, there's the sense that the bill has not received sufficient consultation with affected communities. Second, there's a concern as to the inclusion of risk group 2. Third, there's the fact that much is being held over to be included in the regulations as opposed to in the legislation and that affected parties should trust that the regulations will be appropriate.

You've been hearing about these concerns primarily from research scientists and lab executives. My comments overlap with theirs, but I'm applying a legal lens to the bill. I'm concerned that aspects of Bill C-11 may be vulnerable to court challenge on the basis of the Constitution, both the division of powers and the Canadian Charter of Rights and Freedoms. I will also discuss the policy question of leaving to regulation significant aspects of the legislation. In each of these areas, I will propose tentative solutions.

On division of powers, the federal government has indicated it is relying primarily on the criminal law power under the Constitution Act to justify entering into a new area of federal jurisdiction. My basic concern is that aspects of this bill may be viewed by the courts as matters of property and civil rights, which fall under provincial jurisdiction. The problems, and I'll deal with each of these in turn, are with overreach, with leaving important matters over to regulation, and with establishing a complex structure that may be viewed as not criminal but regulatory.

First, then, is potential overreach. The full title of Bill C-11 is “An Act to promote safety and security with respect to human pathogens and toxins”. Note that it's aimed both at biosafety and biosecurity. Thus, there are risk groups ranging from 2 to 4, the highest being clearly biosecurity, preventing the substances from being used for purposes of terrorist activity. This is clearly a national security matter and falls comfortably under the federal criminal law power.

As the risk groups go down in level, one might conceive that they are more broadly focusing on biosafety—preventing accidental releases that could cause harm—and less on biosecurity. The greater the focus on biosafety as opposed to security, the more likely that the scheme is intended to regulate labs utilizing these materials and the less it appears to be a criminal measure. The inclusion of risk group 2 human pathogens and toxins, a number of which can be found in our natural environment, tends to look like a matter of provincial jurisdiction.

Second is leaving important matters over to regulation. The Governor in Council under this bill is given very broad regulation-making authority. That's paragraph 66.1(c). Further, very much of how this act is going to operate, how facilities will be licensed and run, what will be the inventory requirements, requirements for security screening, etc., have all been left over to be included in regulations to be drafted at a later date. In fact, Mr. James Gilbert indicated to this committee that the act itself is a shell and the details are to be in the regulations.

In law, the more the heart of the matter is contained in regulations as opposed to in the legislation itself, the more the scheme appears to be regulatory in nature, and thus under provincial property and civil rights powers, and the less it appears to be criminal.

Third is sophistication of the regulatory scheme, and this overlaps with the topic I was just discussing. There's one blanket prohibition in the act and that's on use of schedule 5 human pathogens and toxins. However, primarily, Bill C-11 exempts a whole series of activities from constituting a prohibited activity, assuming certain conditions are met, such as licensing. It gives authority to administer these matters to inspectors, analysts, biological safety officers, etc. This is the third way in which much of the bill appears to be more regulatory, in setting out this complex regulatory scheme, than criminal in its orientation, leading again to the question of whether aspects of the bill fall under provincial jurisdiction.

The three topics I've just identified as giving rise to issues of division of powers...in order to avoid problems with them, I suggest that risk group 2 either be completely removed from the scope of the legislation or restricted to the subject of importation in a separate section, and also that more substance be included in the legislation and not held over to be addressed in regulations.

● (1535)

I urge that the time be taken to sort through the substance of this legislation. I see no reason for haste in this matter and plenty of reason to undertake comprehensive consultations. This is a brand-new field for the federal government in certain respects and the time should be taken to get it right.

Those are my submissions on division of powers. I'll now address policy concerns.

The essence of my concern is that it is not appropriate to leave substantial aspects of the legislation to be decided by regulation. This is separate and apart from the argument I made a minute ago regarding why this leads to questions as to whether the bill is criminal in nature.

The nub of my argument here is that the legislative branch of government should not be delegating authority to the executive branch to define many aspects of the functioning of the scheme. One example of this is that there are risk groups ranging from 2 to 4. We know it's prohibited to handle materials in schedule 5, but for risk groups 2 to 4, there is not a single part of the bill in which the difference as to which risk group applies is identified.

In other words, major aspects of how this bill will work are opaque. This has led many of the witnesses, as well as at least one of the provinces, to express the concern that they're not being told enough about its workings and impact.

Bills receive serious scrutiny prior to becoming law. Indeed, this committee is one of the important protections against there being bad laws enacted. Further, there is the scrutiny of the public as reflected in debates of the House of Commons and Senate. On the other hand, regulations are enacted by the Governor in Council, meaning essentially that cabinet gets to decide what is in regulations.

The ease with which regulations can be enacted, varied, and annulled at the whim of the government of the day should sound a major note of caution to the committee. These matters should be in the legislation itself.

In terms of solution, the same solution as in paragraph (a), the division of powers, is suggested; that is, hold consultations with the communities of interest and then develop a bill that includes its full substance, leaving merely the administrative matters to be dealt with in the regulations.

Next, and finally, there is the Canadian Charter of Rights and Freedoms. The charter limits the discretion of the government in that it grants persons rights against certain actions of government. If legislation intrudes on these rights in a manner not justified in a free and democratic society, it may be struck down as being of no force or effect. Thus, it is important that the bill in its entirety not violate the charter. In particular, I'm concerned about the right to be protected against unreasonable search and seizure under section 8 of the charter.

Privacy is a protected right under the charter in a variety of contexts, notably the right against unreasonable search and seizure in section 8 of the charter. Clause 38 of this bill grants the minister very broad powers to compel the supplying of personal information that, in his or her opinion, is required. Note that there's no requirement for reasonableness. The minister, in turn, is entitled under clause 39 to disclose this information without consent to a wide range of parties, including to foreign governments, for a wide range of purposes.

Clause 41 allocates similarly broad powers to inspectors to search places or conveyances and to seize materials found there. None of this is on the grounds of reasonableness in terms of requiring the information or materials. Further, there is no confidentiality clause in Bill C-11.

I propose that these powers be more closely circumscribed. The bill should identify in much greater detail the specific types of information the minister may compel and the purposes for which the information can be utilized, including the disclosure abilities. It should also indicate that the least amount of information in the most de-identified form necessary for the purpose be collected, used, or disclosed.

Further, the requirement of reasonableness in the compelling of information should be incorporated. The more criminal in nature the activity under review, the higher the requirement that there be a reasonableness component. It's important that the powers of search and seizure, or at minimum the more intrusive powers of search and seizure outlined, be exercised on grounds of reasonable suspicion.

● (1540)

The Chair: Ms. Gibson, I just want to say that you're almost at 10 minutes. Go ahead, just to finish.

Ms. Elaine Gibson: I have maybe three more sentences.

Wording should be added to this effect. Also, a confidentiality clause should be added to the bill that outlines broadly a duty on all parties to keep personal information confidential, subject to other provisions in the bill.

I note that the federal Privacy Commissioner, in a letter to the committee, has expressed a number of concerns and the need for further consultation, including a privacy impact assessment. I concur with her comments.

Thank you.

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

Now we'll go to Roland Leitner.

Mr. Roland Leitner (Occupational Health and Safety Consultant, As an Individual): Thank you very much for having me here today.

I did not prepare extensive briefing notes as my colleague did, but I would like to tell a little bit of my story.

I was hired by the University of Calgary over 23 years ago. I became a biological safety officer shortly thereafter. When I started working for the University of Calgary, the issue of biological safety was non-existent. We had researchers working throughout the university with materials. The university, which was somewhat responsible for what was happening in its facilities, did not know who was working with those materials, where they were working with them, or what those people were working with. In other words, the university was in no position in any way to know what was going on or in any way to try to contain it.

Over the past 23 years I have been successful in introducing a system that allows the university to know what is being worked with, where it is being worked with, and so forth. Initially the response from researchers was that because they were microbiologists, they knew what they were doing, and therefore there was no need for regulation and no need for any guidance whatsoever. I found in the meantime that this was more bravado than actual knowledge of how to work with biohazardous materials.

It reminded me, in retrospect, of the introduction of nuclear substances into research programs. In these situations researchers were using nuclear substances as tools to achieve certain outcomes without having any background on the work. That is even more the case nowadays; a lot of biohazardous materials are used as tools to establish certain outcomes without any knowledge or background on the part of the researchers on the potential hazards of those materials.

When the importation legislation referring to laboratory biosafety guidelines came in some time ago, for the first time we had an inkling of what such regulated work with biological materials would look like. Many of our laboratories are level 2 laboratories. One problem researchers had was to understand that containment level 2 laboratories do not need as much in terms of requirements as they would originally say they would need. There was a preconception that any work they did with level 2 materials required expensive equipment, which is simply not true.

The situation that has existed from the time we had the importation legislation up until now is similar to requiring only the drivers of vehicles that are imported into Canada to have insurance, to have a licence plate, and to follow the rules of the road, while no one else has to meet those requirements at all.

My university is in full support of this legislation. We'd like to get a clear picture of what it looks like. Let me assure you that in times of financial restraint of the kind we are going through right now, it is the issues that are legislated that receive the attention of people at universities and other institutions. There's a good case to be made that anything that works with nuclear substances is going to be addressed and anything that is regulated is going to be addressed, but biological safety is not being legislated to that degree and would not be addressed to that extent.

Thank you very much.

● (1545)

The Chair: Thank you so much.

We'll now go to Raymond Tellier.

Dr. Raymond Tellier (Medical Microbiologist, Associate Professor, As an Individual): Thank you very much, and thank you for the invitation.

I don't have a very extensive presentation, but I have a few comments, nonetheless. I came here more prepared to answer questions.

I'm a medical microbiologist, and I spend a considerable part of my time working in diagnostic microbiology laboratories, so my reading of the bill has been very much coloured by that experience.

I think legislation that clarifies these issues and provides clear regulation and has the tools to enforce them is something that is welcomed overall. However, we ought to be cognizant that this legislation is proposed in the Criminal Code, which has very broad power, and if it is not done right, it's going to cause considerable problems.

It may cause a definite chill in the scientific community, especially in light of recent events in the microbiology community in the United States following the legislation of biosafety and biosecurity they have introduced—I'd be happy to go into the details on that. I think we can agree that it's important to do it right.

Personally, I was very much comforted during the consultation we had with the civil servants and the PHAC and other agencies in which they indicated they very much want to continue their historical approach, which has been one of cooperation and education rather than coercion, but to nonetheless have the tools available in cases where it is necessary. I must say that having seen the proposed changes and the changes in the law that has followed the consultation, I'm very much encouraged in that regard.

It is important to realize that the danger of legislation that is too strict is an inhibition or paralysis of diagnostic microbiology laboratories, which would have important adverse effects on the health of Canadians being treated in the hospital. Not only are many Canadians hospitalized primarily for infections, but infections are one of the most common complications of many of the other therapies we have, be it organ transplantation, cancer treatment, surgery, etc. It is very important for public health, and for the health of Canadians, that the diagnostic microbiology laboratories be able to do their work.

With respect to a few notes that I made on the bill, the clarification that many of the regulations concerning the handling of risk 3 and 4 pathogens, or even risk 2 pathogens, does not apply to natural samples such as a human patient actually infected with the disease or samples that are taken for laboratory testing is very much welcome.

I think there are problems with the schedules that list the organisms. They have been improved throughout the process, but they still contain mistakes and many surprising omissions. Even if they were perfect at this point, it is the nature of the field that this list must be regularly updated because of changes in our knowledge or changes in the objective circumstances. It is important that the schedules be updated easily and that they not be cast in stone.

I don't know all the technicalities of overlap of jurisdiction, but I was also concerned about the licensing issues for diagnostic laboratories. There are already licensing processes at the provincial level that are in place. Speaking as a very busy laboratorian whose resources have been cut over the years, it would be very welcome if these processes could be synchronized so we could do licensing at one time in the year and not spend our time moving from one licensing process to the other.

I think the revised licensing for risk group 2 pathogens has been considerably streamlined, and it's very encouraging in that regard.

● (1550)

There is a lot of concern among all of us about the inspectors. They will apparently carry considerable power, and we are a little concerned about their scientific background and training, and making sure their powers are used judiciously.

From the point of view of diagnostic laboratories, I am concerned about the power inspectors have to make copies of any records. In diagnostic labs many records contain names of patients, what the samples are, and what they have been tested for. You can well imagine that you'd like to keep some micro-organisms more private than others. But whatever is the case, there is very stringent privacy protection legislation that we have to obey in diagnostic laboratories, and it seems to me there's a conflict there.

That's all I have to say for now. I came mostly prepared to entertain questions rather than give an extensive presentation.

The Chair: Thank you very much.

Dr. Butler-Jones.

Dr. David Butler-Jones (Chief Public Health Officer, Public Health Agency of Canada): I'll be very brief because we want to leave this opportunity mostly for questions. I will ask Jane to speak to the legal points. I'm obviously not a lawyer, and that's probably a good thing.

On the issues of privacy, etc., we are clearly subject to that. The list of pathogens is illustrative. It is not intended to be either exhaustive or represent what would be included in the regulations, which require broad consultation. That's part of the reason why the legislation is so broad. In the consultations we were told that a number of things really need more specific direction. They need to be in the regulations rather than the legislation so they can be modified to respond to the changing science.

I'm going to leave it at that. I think Jane should speak to some of the legal points that have been raised.

Back to you, Madam.

The Chair: Ms. Allain.

Ms. Jane Allain (General Counsel, Legal Services, Public Health Agency of Canada): Hello.

Well, the first thing I want to underscore is that, as you probably no doubt know, health is not a distinct head of power enumerated in our Constitution Act, and essentially you have to look at other heads of power to see how it fits in. There are several heads of power that support federal legislation in relation to health. Ms. Gibson is correct that we are primarily relying on our criminal law power for Parliament to enact Bill C-11.

Criminal law power used by Parliament can be valid health-related legislation provided that it addresses a valid criminal law purpose, such as the protection of public health. We believe that Bill C-11 does so by trying to criminalize certain behaviours dealing with human pathogens and toxins. It's backed by both a prohibition and a penalty. And Bill C-11 does have various prohibitions in clauses 6, 7, and 8 of its statute, and the penalties are set out in clauses 53 to 58.

Parliament has used criminal law power to enact various legislation that is somewhat similar in the way this specific bill is designed, and these various pieces of legislation have been supported and upheld by the Supreme Court of Canada. The Canadian Environmental Protection Act is an example, as well as the Food and Drugs Act, the Controlled Drugs and Substances Act, and the tobacco products control act.

The other thing I would like to underscore as well is that the penalties found in Bill C-11 are quite similar in scope to others that we received and modelled against, to a certain extent, such as the Quarantine Act and the Canadian Environmental Protection Act.

With regard to the charter provisions, the Minister of Justice has the responsibility under section 4.1 of the Department of Justice Act to always ensure that bills that are tabled in Parliament have had a charter review. As a result, when the Department of Justice looks at legislation as our clients are developing them through the policy development as well as the actual drafting, we do look at those provisions and ensure that it's charter compliant. We look at things like the search and seizure provisions to ensure they are compliant with section 8 of the charter. I can assure you that such a review was done by the Department of Justice for this piece of legislation, and in fact the inspection powers are quite similar to other pieces of legislation that currently exist, whether it's the Hazardous Products Act or the Quarantine Act.

With regard to the privacy concerns, the other aspect I wanted to underscore is that the agency is still bound by the Privacy Act and the requirements that are imposed by the Privacy Act, which, as I mentioned before, include the minimal collection as well as the minimal disclosure principles, and the department will have to comply with those provisions as it develops its regulations. In fact, for the disclosure of documentation to a foreign body, there is a requirement to get written assurances that they will maintain the confidentiality of that information. So that protection does exist in this legislation.

Those were the main points I wanted to underscore on the constitutional aspects as well as the charter.

With regard to the Governor in Council making regulations, it is in fact a delegation from Parliament to the executive, as Ms. Gibson has indicated. But I would not say it's done in secrecy. In fact, there is quite an extensive requirement for the department to go out and consult, to prepublish their regulations as they will be developing them, and then to reply back in terms of the consultation process. That's in the Canadian gazetting process, and the department has indicated quite clearly that it intends to follow that model.

● (1555)

The Chair: Thank you.

Dr. Tam, did you want to make any comment?

Dr. Theresa Tam (Director General, Centre for Emergency Preparedness and Response, Infectious Disease and Emergency Preparedness Branch, Public Health Agency of Canada): No.

The Chair: Okay. We'll go directly to the questions. The first round is seven minutes for the question and answer. We'll begin with Dr. Bennett.

Hon. Carolyn Bennett (St. Paul's, Lib.): Thank you very much.

Ms. Gibson, I found your testimony very thoughtful, and I thank you for having read all of the other testimony and summarized for us. I think you summarized very closely to what a lot of us have been concerned about. We take the responsibility of the committee to get this bill right.

I guess my first question is on the proposal that the government will show us their proposed amendments tomorrow afternoon and then we would vote on clause-by-clause on Thursday afternoon.

Do you think this committee would have done its job properly if we agree to go to clause-by-clause on Thursday afternoon?

Ms. Elaine Gibson: In the evidence of the witnesses so far, I haven't heard a compelling argument as to why this bill should not be put on hold and that consultations happen and the legislation made much more complete. I have not heard a pressing need to proceed quickly with this bill.

● (1600)

Hon. Carolyn Bennett: Certainly, that is my feeling. There were many concerns, and the amendments are supposed to remedy those concerns. I would feel better going back to the people who expressed the concerns to find out whether the amendments fix them.

I was also concerned to read the summary of sessions with stakeholders, and to see reiterated the difference between information sessions and consultation. A lot of the concerns that were raised by the witnesses are clearly here in the stakeholder summary, but they are not fixed in the bill. The response from the Public Health Agency of Canada said the legislation would provide clear definitions, but it doesn't. When people asked how they'd know whether their concerns were reflected in the bill, the Public Health Agency said this would come out in their consultation strategy.

Here it says that people who've been in the country for ten years won't be cleared. For all the laboratories, clearances should be good for five years. Students could perhaps work without a student security clearance if a supervisor were authorized.

As a legislator, I find it hard to trust that all this will be fixed in the regs. They tell us not to worry, that they'll fix it in the regs. We also have the situation with the Assisted Human Reproduction Act, where we specified that the regs would have to come back to this committee. We've only ever seen one chapter, and the whole thing has been on hold.

PHAC responds that there is no policy intention to capture non-pathogenic agents. If non-pathogenics are eventually captured, schedules could be changed by ministerial regulation. That is what everybody is hugely worried about. With respect to polio, they say it's not in the schedule, but, when banned worldwide like smallpox, it will go in schedule 5 of the bill. It's 2009. I don't understand how you can leave out polio.

I am asking the department what they have to say about Ms. Gibson's serious concerns. What's the hurry, and why can't we just get this right? Why can't we put what must be in the bill, in the bill? Why can't we send to regulations only those things that need to be flexible?

Dr. David Butler-Jones: As a result of the consultations on the previous bill, which was more specific on a number of these items, we were requested to make this one less specific. The view was that with the changing science it would be better to have the act in place and then work through an intensive, clarifying consultation on the regulations. This act responded to that view. Now some people think it should be more specific—when we were responding to a request to make it less so.

As to the specific clarifications and amendments required to address the concerns that people have raised, that's a legislator's decision. But that's how we got to this point. It was in fact an honest response to the consultations, and it was drafted so as to recognize the request from scientists and others to make it less specific. Now we're back on the other track.

The issues that have been raised are not new. It's just that we feel we can address them through the regulation, which is a public, transparent process. We want to make sure that we get the application of this right at the end of the day.

Thank you.

● (1605)

The Chair: Ms. Allain, would you like to make a comment?

Ms. Jane Allain: The main point that Dr. Butler-Jones was referring to was with regard to the scheduling of the pathogenic material. Through the consultation, initially, it could have been a Governor in Council scheduling amendment, but we reflected the changes so that the minister, through expert advice, would now be able to change the schedules. It allows that flexibility and adaptability, because if you do a Governor in Council regulation as opposed to a ministerial regulation, it's more onerous. That was the main point that Dr. Butler-Jones was making.

Dr. David Butler-Jones: As well as the difference between level 2s, 3s, and 4s.

The Chair: Thank you very much, Dr. Butler-Jones and Ms. Allain.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Once again, I would like to thank our witnesses for being with us today. New witnesses always enrich our discussion of issues, and I thank you for that.

Ms. Gibson, you said since the federal government is getting into a new field under Bill C-11, it would be much more reasonable, in order to comply with the Constitution and the Charter, to limit the scope of Bill C-11 with respect to group 2, and that more items be included in the legislation, rather than in the regulations. If the opposite were done, there would no doubt be some court challenges to the bill's constitutionality.

For her part, Ms. Allain, from the agency, seemed to say that there was a consultation process and that areas of jurisdiction under the Constitution will be respected.

Just listening to you, I see a constitutional battle looming, because the two viewpoints are at odds.

I would ask you each to present your arguments again and explain the reasons for them.

[*English*]

The Chair: Ms. Gibson.

Ms. Elaine Gibson: I am not saying with certainty, and I would be foolish to say with certainty, that this bill is unconstitutional, so please don't misread me on that. I'm raising some concerns about its constitutionality, both on division of powers and on charter grounds. The charter argument is more limited, and it has to do with the powers of search and seizure and the powers of compelling personal information in the statute. I believe they are overly broad and that the reasonableness standard needs to be incorporated.

Did you receive a copy of the submission of the federal Privacy Commissioner? Okay. Some of my concerns are also elaborated upon by her. So that's the charter portion that I was addressing.

When it comes to division of powers, there's a case out of Quebec that overturns the majority of the Assisted Human Reproduction Act on the basis of division of powers. It's a Quebec Court of Appeal judgment. It's being heard before the Supreme Court of Canada, so the law is quite unsettled. If you look at that case, you will see that the types of activities are very similar.

The claim of the federal government was to justify it under the criminal law power, and the Quebec Court of Appeal says they don't find that significant portions of it fall under the criminal law power, that in fact the prohibition sections certainly do, as well as some others, but the broad licensing scheme does not look like what they referred to as an evil that needs to be addressed, and that in fact assisted human reproduction is something we want to promote. That is very similar to the use of laboratories' use of these substances, and the licensing and inspection procedures, etc., are very similar to what happened under the Assisted Human Reproduction Act.

We don't know yet what the Supreme Court of Canada will say on this. They do tend to give very broad discretion to what can be found to fall under criminal law power. On the other hand, this decision will be coming sometime in the next year, presumably, and we'll have much more guidance. For the moment, we know that the Quebec Court of Appeal says that a scheme very similar to this one, with all its licensing provisions, is unconstitutional in terms of division of powers.

● (1610)

[*Translation*]

Mr. Luc Malo: As I understand it, there may be lawyers fighting over this in court, rather than parliamentarians reviewing the bill, because there are—

[*English*]

The Chair: Monsieur Malo, would you be so kind? I didn't notice Dr. Butler-Jones—

[*Translation*]

Mr. Luc Malo: Go ahead.

[*English*]

The Chair: Is that okay? Thank you.

[*Translation*]

Dr. David Butler-Jones: I had a conversation with [*Editor's Note: Inaudible*] in private. He now seems to assess the program favourably. That is the best place for this, if the reasonableness test is met. The provisions in this bill are also found in existing legislation in Canada.

Ms. Allain.

Ms. Jane Allain: As Ms. Gibson said, the Assisted Human Reproduction Act is before the Supreme Court of Canada. The Government of Canada is firmly convinced that it is constitutional, and that the ruling by the Quebec Court of Appeal is not in keeping with the Supreme Court's case law as to what Parliament can do with respect to its criminal law power. We believe that the full text of all bills of this type, which contain criminal sanctions and prohibitions, must always be reviewed.

The problem is that in making its ruling, the Court of Appeal deciphered and dissected the bill. We think this is the wrong approach, one that has not been supported by the Supreme Court of Canada to date. We feel sure we will win the case before the Supreme Court of Canada, as we usually do, but I do not want to argue that case here.

Mr. Luc Malo: Is the objective to send legislation to the court and go as far as possible so that you always get a little more?

Ms. Jane Allain: No. The objective is to legislate in an area in which Parliament has been able to legislate to date and to do it in the appropriate manner. We always conduct an exhaustive analysis—and I can certainly confirm that—with our colleagues in the department.

Mr. Luc Malo: In that case, if the provinces—

[*English*]

The Chair: Thank you, Mr. Malo.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you, Madam Chairperson, and thanks to all of you.

I want to break this down into four areas, which I think we have heard are major concerns, and ask the non-departmental health officials to respond first. Then I'll ask Mr. Butler-Jones and Theresa and Jane to respond.

The first has to do with the concern that this bill is so focused on biosecurity that it is indiscriminate in terms of the types of pathogens and toxins we're dealing with and therefore will hamper research in this country. We've heard that over and over again. The last reference that we had was to what happened in the United States under legislation similar to the Patriot Act. In that case, researchers have decided to discontinue or not pursue research on regulated biological agents rather than implementing the new security regulations and bearing the associated financial burden.

That's my first question.

Do the witnesses have a comment on that aspect, and do the Health Canada and public health officials have a response to those concerns?

● (1615)

The Chair: Dr. Butler-Jones, or Mr. Tellier, were you first? Go ahead, Mr. Tellier.

Dr. Raymond Tellier: This is certainly a concern that is raised by the legislation. It's a little difficult to address it completely until we see the regulations, but I agree with you that a danger of such a bill is that with indiscriminate use it can result in a chilling effect on medical research, on diagnostic activity, and it can result in injustice. Unfortunately, these things have happened in the United States, where the effect of the Patriot Act has been an exodus of research on organisms that are on the special organism list in this legislation because many researchers see it as not worth the trouble and the danger of inadvertently being found in infraction. There is the case of a distinguished microbiologist, Dr. Butler, who ran afoul of one of the provisions of the Patriot Act, which he himself reported. The consequences were very severe in terms of imprisonment and loss of his medical licence and position at the university. Yes, there is a concern.

At the same time, if this legislation is done correctly, if a clarification is done that could be beneficial, I think that certainly for risk group 2, which is the immense majority of the micro-organisms being handled in diagnostic laboratories and in research, the evolution of the consultation seems to me to be moving in the right direction.

Risk group 4 is handled only at the international microbiology laboratory in Winnipeg, so the federal government can regulate itself to its heart's content, I would think.

Risk group 3 is perhaps where we'll have the most problems because several organisms in there are very dangerous. That's why they're there. They need to be regulated correctly. At the same time, the laboratories of level 3 are becoming more and more common for both research and diagnostic purposes. We need only to remember that over the past few years Canada has seen major outbreaks with level 3 organisms: the SARS epidemic in Toronto and Vancouver, and the introduction in North America, including Canada, of the West Nile virus. Both of these viruses are risk group 3.

Also, something that is not addressed specifically in the legislation but is being seen considerably in research is the use of viral vectors with genetic construction that could, in theory, cause cancer, and these are to be handled in level 3 laboratories. So what we have been seeing over the past several years is an increase in the number of level 3 laboratories in the country, which overall is a good thing because they do respond to a need, but they have to be operated properly in both senses of the word. You must not end this work that needs to be done for medical research and for public health, but at the same time we have to be sure no reckless work that could pose danger is being done.

The Chair: Would anyone else like to comment?

Ms. Gibson.

Ms. Elaine Gibson: Just very briefly, health researchers in Canada took a hit in the last federal budget, so already there is a concern that some of them may leave Canada for greener sites for conducting research. The concern about the increased cost to researchers is a valid concern. We're being told this will be dealt with in the regulations, but we don't have enough information on that at the moment.

The Chair: Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: I want to go now to David Butler-Jones and Theresa Tam about this particular issue because they have heard it before. We've talked about how we can separate level 2 pathogens. Can you make a proposal at this time?

Dr. David Butler-Jones: Certainly through the regulations the intent is that for security clearance it would not apply to level 2. It would not even apply to all level 3 pathogens.

I'll turn it to Theresa just to mix it up a little bit.

● (1620)

Ms. Judy Wasylycia-Leis: While you are answering that, could you answer whether or not you are contemplating anything in the legislation that would help clarify this so that we don't have to trust that the regulations will clarify the issue?

Dr. Theresa Tam: The Public Health Agency is receptive to clarifications or assurances that we will treat risk group 2 differently from risk groups 3 and 4. We certainly agree that there has to be a degree of flexibility for risk group 3 so that in the regulations and through consultations we can distinguish those of high lethality and impact versus TB or HIV or others in risk group 3 that could essentially be handled differently.

We do want to take a measured approach to risk group 3. It is meant to be risk based.

I just want to reiterate that the legislation is a made-in-Canada solution built upon our existing laboratory safety guidelines, and those distinguish very clearly the differences between risk group 2 and groups 3 and 4.

Then I think the laboratories were concerned about the security aspects and the added burden as a result of that. We did include wording in the current legislation that indicates a security clearance for select pathogens and toxins. It gives consideration to flexibility on risk group 3. Again, the agency is receptive to proposals in terms of more specificity or clarification around that point.

The bill actually does indicate that those who don't have a security clearance can be supervised by those who have. That is currently included in the wording of the bill.

I think the cost, especially in these current economic times, is a concern. Through the regulation and program development process we envisage a reasonable timeline. While we cannot predict what the economic climate will be in five years' time, we would want to approach the implementation in such a way that we can actually take into account the circumstances and the context in which laboratories are working so that they will have time to adjust to certain requirements.

The Chair: Thank you, Dr. Tam.

I believe, Mr. Leitner, you want to make a few comments. Then we'll go to Dr. Carrie.

Mr. Roland Leitner: Very briefly, our university operates one containment level 3 laboratory that works with various agents that are on the international list of warfare agents. Some, if not the majority, of research with those agents even in Canada is funded through the United States Army Medical Research Institute of Infectious Diseases.

As such, our laboratory has to, and has had to, comply not only with Canadian requirements but also with the requirements of the legislation that you brought up, the Patriot Act. As such, we've had to provide security clearances for the people who access that laboratory. My experience was that it was a very fast process. The process didn't cost us anything other than a little bit of delay. It certainly did not turn out to be as onerous as was originally anticipated by the laboratory.

This is certainly something that some of the laboratories in Canada already comply with if they work with those agents, and it is far less onerous than other people have been led to believe.

Thank you.

The Chair: Dr. Carrie.

Mr. Colin Carrie (Oshawa, CPC): Thank you very much, Madam Chair. I want to thank the witnesses for being here today.

I'd like to talk about the issue of consultation for a couple of moments, Dr. Butler-Jones. I have taken a look at the four years that you did work on different consultations; some people called them information sessions. I think Dr. Tellier and Dr. Leitner said they were consulted in the process. There has been talk in the committee about provincial and territorial consultations. I know we got a copy of a letter from British Columbia.

I was wondering if you could comment. Have you been in contact with British Columbia? Was there a difference between the political content of the letter as opposed to that from government officials in your conversations or communications and consultations with B.C.? Was the letter we got dated, and is it common to date those?

● (1625)

Dr. David Butler-Jones: It's not common to have undated letters, but in terms of one of the things as we move forward, B.C. is an important partner for us through the B.C. Centre for Disease Control, as well as the Ministry of Health and its divisions. They have been very much engaged through this process, but not every single person in the departments has been engaged to the same degree.

We've had a number of conversations since then, including conversations with all the chief medical officers across the country, plus the provincial lab directors and others, sort of building on the previous conversations. I think all of them are looking forward to whatever happens. Obviously, as officials we're not going to preempt your legislative process. We are open to clarification and other things as you work through the next few days.

But at the same time, as we develop the regulations, they are really looking forward to the process of consultation that we've outlined, and their engagement in ensuring that the consultation and the process that follows will be comprehensive and effective, as we've described. All the conversations I've had with provincial officials and others is that they will do that. That, they see, is a way forward. We think we've addressed, and we will continue to address, the concerns in a way that is reasonable.

We have responded formally—I think the committee may have a copy of the letter in response—as we have responded to each of the others that have written to us.

Mr. Colin Carrie: That's what I was going to follow up with. In your opinion, in regard to when the original letter was written, do you feel there's a greater understanding of the intent now, as opposed to when the letter may have been written? Can you comment on that?

Dr. David Butler-Jones: I think so. Again, we all have large systems and multiple players, and some of us have multiple departments. Even though I had talked to the deputy with the broadest responsibility in this area and the chief medical officer and others, not everybody at that point was aware of it.

We received the letter, and since that time we have had conversations with the deputy on that side and others. We'll continue that dialogue as we move forward. I think there's a level of comfort in that process as we address these issues.

Mr. Colin Carrie: There was an issue about doing the regulations afterwards. I was wondering about that. Are there precedents? Have we done this the same way in the past? There seems to be a concern among some people who say they want to see the regulations now. Maybe it's the Quarantine Act. We talked about the Assisted Human Reproduction Act. Is there a precedent that says the government has done it this way in the past?

Ms. Jane Allain: The normal process is that you get Parliament's authority, essentially, to make the regulations. The normal process is for Parliament first to enact the statute. Then the secondary legislation, which is the regulations, has a process whereby it's been authorized by Parliament for us to do it. The normal process is for the act to be passed and then the regulatory framework is developed. Through the consultation process and through the gazetting process, that's done.

There are examples, such as the Assisted Human Reproduction Act, for example, where, as you have all noted at different points, the House of Commons and the Senate.... There is an explicit provision in this statute that requires the government to come back and table its regulations before they're made, before both Houses. It's not a very common amendment, but that type of provision does exist.

Mr. Colin Carrie: Subclause 3(2) of Bill C-11 states that for the purposes of this act, “a human pathogen or toxin includes (a) a substance that contains a human pathogen or toxin”. Clause 4 of the bill also provides that the act doesn't apply to “a human pathogen or toxin that is in an environment in which it naturally occurs if it has not been cultivated or intentionally collected or extracted”.

There was a comment that waste treatment facilities commonly collect and treat water that contains human pathogens or toxins. The waste water is in a natural environment for human pathogens and toxins, so according to clause 4 of Bill C-11, the act does not apply to these. Dr. Tellier also brought up a point about patients who perhaps have diseases that have these things as part of them. Is it possible to consider these facilities as substances under clause 3 of Bill C-11 so as to include them under the act?

● (1630)

Dr. Theresa Tam: This is actually a conversation that we've had with water treatment facilities, and we certainly consider waste water that is collected and contains pathogens to be a natural environment. To us this is clear in the bill as it exists.

So you do have to interpret the bill, and its different sections, in its entirety. We had no intention of considering a facility that is not cultivating and extracting these pathogens as falling under the scheme. I think that's clear.

We have exemptions, and those exemptions came after we heard the concerns expressed in the consultations stage of the initial draft of Bill C-54, but we also have a provision that we can make further exemptions in the regulations themselves.

We truly believe that as more stakeholders come forth, different scenarios may come up in the future, because some of these labs are not known to us. So having that provision allowing further exemptions in the regulations, if needed, is built in.

The Chair: Thank you, Ms. Tam.

We're now going to go to our second round, a five-minute round of questions and answers, starting with Dr. Duncan.

Ms. Kirsty Duncan (Etobicoke North, Lib.): Thank you, Madam Chair.

Good afternoon, everyone.

I think we all agree that biosafety and biosecurity are of paramount importance and that we have to get them right. I think there is also a real concern, after the testimony of the last weeks, that we're perhaps rushing this. We've had real recommendations, which are in that document. We've heard similar testimony.

Is it possible to take this back and do more consultations and to incorporate the recommendations and testimony and make it stronger, because the issue is so important? Is that possible?

The Chair: Dr. Jones.

Dr. David Butler-Jones: I'll just start on that and maybe I'll get Theresa to speak to the importance of why we should do it now.

In this process in the committee, it sounds as if you will perhaps be considering some ways to make the legislation clearer in terms of our intent. Our intent is clear. I'm on the record, we're on the record, the government is on the record on how we plan to proceed. Quite honestly, my personal integrity is on the record in dealing with this. But no legislator should depend on that; I'm not suggesting it at all. If there are ways to make that intent clear and explicit in the legislation, obviously we would welcome that.

I would be concerned about further delay beyond that, taking it back and starting over. There's been work on this and the need for it has been recognized for at least a decade. There has been work around animal pathogens. We are better at controlling animal pathogens in this country than human ones, or have a better understanding of the things that kill sheep and cattle in this country than humans, when it comes to regulation. We do regulate imports and exports. We do regulate transport of these things. But at half the labs in this country, nobody really has a clear handle on this.

So in terms of the importance of this, I'll turn to Theresa and then will come back to you, Madam.

Dr. Theresa Tam: I think looking at further assurance, if you like, in the legislation is certainly something we would be prepared to look at. We haven't rushed into this. We have had human pathogen importation regulations for 15 years. The concept of the need to know who possessed what domestically and how we could safely handle these pathogens took place around 1999. Then came the anthrax scare, then came SARS. Nobody knew who possessed the SARS virus. Then the drafting of the legislation began in 2004.

I think the concerns we've heard are the ones we've heard before. We certainly feel that they can be taken care of in regulations. But if we can provide further assurance in some way, then that is good. The proposed program and regulatory framework are also posted publicly on our website.

I think every other day something else happens. The H2N2 distribution happened. Something could happen tomorrow. Someone talked about the polio virus and about the fact that we don't know where the polio virus is in Canada. It's important; I would like to know—by tomorrow, if possible—exactly who in Canada has the polio virus.

While it is not specifically in the schedule, it is captured under the risk group definitions. You can provide examples, but you will always leave out certain examples, or be more inclusive in the list than perhaps others wish. But you don't want something to happen tomorrow, and within the experience of our programs....

A few weeks ago—in “a” province—we came across a laboratory that was abandoned, with nine freezers full of pathogens. In another province, an “underground” laboratory was discovered, and we had no ability to necessarily regulate. There are very non-uniform practices.

I think the good academic labs that have biosafety programs in place are again the ones that we feel could comply with the legislation rapidly. But what you don't want to see is that these other laboratories have issues that will arise without our taking care of it, having thought about this for ten years.

● (1635)

Ms. Kirsty Duncan: I agree, and—

The Chair: I'm sorry to interrupt you, but your five minutes are up.

Dr. Tam, thank you.

We will now go to Ms. Davidson.

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Thank you, Madam Chair.

Thanks very much to our presenters this afternoon.

We keep hearing some of the same things over and over again. Some are new things and some are different things, with maybe variations of some of the same concerns. But we are also hearing today answers to a lot of these concerns.

Ms. Gibson, you outlined some of your specific concerns—comprehensive consultation, risk 2 listings, jurisdictional issues that you felt were there, and maybe some Charter of Rights issues. In terms of the things you've heard today from departmental officials, what they've discussed and what they've given answers on, have they answered any of your questions or made you feel any differently from when you first came into the meeting?

Ms. Elaine Gibson: I am sorry to say, not at all.

Mrs. Patricia Davidson: Could you maybe say why?

Ms. Elaine Gibson: Well, I think I had a pretty clear indication of the position of the Public Health Agency of Canada based on the presentations they've made to this committee and based on what I've read in the minutes up to now. I am not hearing anything substantially different today.

I think the substance of my concern could be summarized as twofold, in the main. Setting aside the charter issues, it would be that holding over to regulation much of the “guts”, if I can use the word, of what is going to happen is problematic. It gives rise to issues of constitutional division of powers as well. If what's really going on here is primarily regulating laboratories in Canada, then that's going far down the road into property and civil rights within the provinces.

Mrs. Patricia Davidson: Okay.

Ms. Allain, I think you've answered these questions, but I would like to hear from you again, if I could.

Ms. Jane Allain: The intention is not to regulate labs for diagnostic purposes or for quality assurances or for how they conduct their business on a day-to-day basis. The purpose of this legislation is to create a scheme that would regulate the possession, use, and disposal of human pathogens and toxins so that they are done in a way that contains them and prevents them from being released in a greater environment to pose a risk to human safety essentially. So that's the basis of the criminal law power. It's not to see the practices on a day-to-day basis for their diagnostic testing. It's to see that their containment levels are appropriate—the steps they're taking to basically prohibit and stop the disposal and disclosure of these human pathogens, these dangerous goods essentially, to a greater audience and to the public at large. And that's the way the scheme is designed. It's not designed for that purpose.

So the reason a lot of things will happen in the regulations is that a lot of them are technical, in terms of the biological safety guidelines and how those will be incorporated into the regulations themselves. That aspect has to be done in technical standards and elements that have to be built up through that process. That's why they have to be done.

I didn't address the other issues Ms. Gibson has raised on the inspection powers, on the charter. The main thing I would say is that on clause 41 there is a reasonableness test there. The inspector has to have reasonable grounds to believe that one of the activities that is prohibited, if you don't have a licence, is going on in that institution before they can actually appear before it. So to us, he has to have reasonable grounds to believe that this is actually going on before he can proceed to that. As well, any kind of inspection power that he or she will exercise would have to comply with the charter, would have to be done in an appropriate manner, because they could be subject to a challenge subsequently. So the standard itself is a reasonable standard and the exercise would have to be done to a reasonable standard.

With regard to the disclosure of information as well, there are both, at different times in clauses 38 and 39, standards that basically refer to it being necessary, the disclosure, in certain limited circumstances that the minister may disclose. It says the minister would, without the consent, only disclose if necessary for the administration and enforcement of the act, and as well if it's necessary to fulfill its international obligations. The minister could also disclose if she has reasonable grounds to believe that the disclosure is necessary to address a serious and imminent danger to the health and safety of the public.

Those provisions are similar to provisions that exist elsewhere that have not been challenged and that we believe are constitutional. From our perspective, a reasonable standard exists for the serious and imminent danger, but a necessary standard is, from our perspective, a higher threshold than a reasonable standard. If something is necessary it's reasonable, but something could be reasonable but not necessary.

● (1640)

The Chair: Thank you, Ms. Allain.

Ms. Elaine Gibson: Could I respond on just one of the matters?

The Chair: Oh, yes, absolutely.

Ms. Elaine Gibson: Thank you. It's clause 41, "Entry by inspectors". I read it in not quite the same way as Ms. Allain was presenting. The reasonableness in there is that the inspector believes on reasonable grounds that an activity, to which this act or the regulations apply, is conducted, not that there be.... I would be pleased if it were that there's reasonable grounds that an offence under this act might be being committed. I would be much more comfortable if that was what it was saying, but I read this as saying that one of the activities covered under this act is happening—i.e., that human pathogens are being used.

The Chair: Thank you.

Monsieur Dufour.

[*Translation*]

Mr. Nicolas Dufour (Repentigny, BQ): Thank you very much. I would like to thank our witnesses for being here today.

Ms. Allain, I have some concerns about respect for federal and provincial jurisdictions in this bill. Scientists and provincial government representatives have noticed this. I have here a letter from Mr. Vivek Goel, who is the President and Executive Director of the Ontario Agency for Health Protection and Promotion. I apologize for my English, but I would like to read you part of it.

[*English*]

> As operators of public health laboratories across Ontario, the OAHPP is already governed under the Occupational Health and Safety Act and subject to inspection for a wide range of health and safety measures pertinent to our staff, up to and including biosafety measures.

[*Translation*]

I would also point out the similarities with the court challenge on the Assisted Human Reproduction Act. In the case of Bill C-11 we see that there will be a court challenge from certain scientists and from the provinces. The same thing happened with the Assisted Human Reproduction Act. The framework of that legislation was similar, and there was a challenge from the provinces. Quebec had warned that it would challenge the legislation, and it did so. This entails legal costs, all the procedural considerations, and time.

Do you not think that the same thing is going to happen once again, particularly since Quebec is not the only province voicing objections? Ontario is, and British Columbia as well. Do you not think you are going a little bit too far? Would you be surprised if the bill were challenged by the provinces?

● (1645)

Ms. Jane Allain: We have had no indication that the provinces were intending to challenge the act or the bill, whereas with the Assisted Human Reproduction Act, we did have the impression that Quebec would challenge it. All I can do is repeat what I have already said. We believe that we are legislating in an area of federal jurisdiction and that the model used here is similar to the one used in other existing federal legislation, such as the Food and Drug Act and the Quarantine Act. Since we are proceeding legislatively, we can never predict whether or not there will be a court challenge. Of course the government wants a bill that complies with the Charter and the Constitution. That is always our intention when we draft a bill of this type with our clients, the agencies involved. We think we will certainly be able to defend this bill.

Mr. Nicolas Dufour: Have you discussed this with the provinces?

Ms. Jane Allain: Yes, there have been consultations with the clients.

Mr. Nicolas Dufour: Dr. Butler-Jones.

Dr. David Butler-Jones: Yes, thank you. I will speak English for greater clarity.

[*English*]

Very quickly, yes, there have been many discussions with the provinces and others. They're making sure, in putting it in writing, that they declare very clearly the issues they want us to address, as we develop the regulations and move forward with this bill, to ensure that we don't have duplicate regimes. We minimize any paper burden on others. We minimize the impact.

The regulation across the country is very variable, and where it is in place, it is by and large related to the occupational health and safety of workers in the workplace and to quality control. It is not about public safety. So this is complementary legislation in situations where provincial legislation exists, and it fills the gap where legislation in no way addresses this.

It is in fact for gaps and is complementary, and we will find ways to ensure that the issues are addressed as we move forward.

[*Translation*]

Mr. Nicolas Dufour: Mr. Tellier was saying earlier that the were many duplications possible regarding licences and inspectors, as Mr. Goel pointed out in his letter, as regards enforcement of the bill at the federal and provincial levels.

[*English*]

Dr. David Butler-Jones: Depending on the province in which they already have an inspection regime, we'll be working with them. Perhaps their inspectors can carry out the pieces of it that their normal legislation doesn't cover. But we won't have specifics until we actually have those specific conversations based on the act we have. We do want to, obviously, minimize paperwork. Because of risk levels 2, 3, 4, which we regulate for imports, we think about half the labs are already under a regulation regime, and for them this would mean minimal change, if any.

The Chair: Mr. Tellier, did you want to respond to this as well?

[*Translation*]

Dr. Raymond Tellier: Just to add a few things.

Mr. Dufour, I certainly expressed some reservations regarding the constitutionality of the legislation, but it should also be mentioned that regulations are required with respect to the use of the various micro-organisms. There could be some serious public health implications, and implications for the health of the people who work in these laboratories. Infections picked up in labs are a real problem. There are examples of this, and Dr. Tam reminded us earlier about what happened with the H2N2 flu virus, which was unfortunately distributed to a number of laboratories throughout the world in a quality control kit. If this virus had gotten beyond the confines of a laboratory, it could have caused a pandemic. The H2N2 virus, which disappeared in 1968, caused a pandemic in the past and could do so again, because everyone born after 1968 has no immunity to it.

I am definitely sensitive to any legislation that could do more harm than good, but there is this need for proper regulations. I would not want us to lose sight of that either.

[*English*]

The Chair: Thank you, Mr. Tellier.

We'll now go to Ms. McLeod.

Mrs. Cathy McLeod (Kamloops—Thompson—Cariboo, CPC): Thank you, Madam Chair.

I would like to thank the witnesses. I really appreciate what Dr. Tellier was just talking about in terms of the fact that there is some urgency. We have been lucky for many years, and I believe there is some urgency and imperative to move forward in this way. I am gaining more comfort as we go in terms of the answers from our department. I think I'm gaining more comfort and confidence that the very real concerns will be addressed through regulations, or perhaps in minor amendments. I will certainly be looking forward to that.

Ms. Tellier, you've worked in many countries. Can you perhaps compare and contrast a little bit in terms of where we're going here versus some of the other countries where you've worked?

● (1650)

Dr. Raymond Tellier: I am sorry, I have not worked in many countries. I have worked in the United States and Canada. In a very broad way, the approaches are similar in most western countries, and that is you have a stratification of the micro-organism in terms of the danger and the confinement level that needs to be approached. Over the years the definition of the laboratory confinement levels 2, 3, and 4 have been pretty much similar.

The classification of the organisms has been by and large similar, although there are differences between countries for some organisms. I could give you an example of some things that are level 2 in Canada and a level 3 in the United States, and vice versa, and arguably these things are properly called two and a half, I guess. But by and large, in terms of the general approach in the stratification of the organisms and the levels of confinement, there are a lot of similarities and I would say an evolution towards a consensus.

What we have seen in the United States in some examples is that sudden, very drastic regulations have appeared that have been very forcibly, and perhaps unreasonably, enforced. I'm proud to say this is not usually the Canadian way.

I think what's also very much clouding the issue is bioterrorism. There's been a concern. You have the issue of containing an outbreak of infectious disease. You have the issue that, for diagnostic laboratories and research laboratories, the handling of these cultures must be done in such a way that they do not pose a risk to the scientific staff and to the population at large. There are also a certain number of organisms that are felt—sometimes for good reason and sometimes for reasons that appear less convincing—to pose a threat of being used for bioterrorism. That's an additional level of concern that has been heightened over the past several years.

The Chair: Do you have any other questions, Ms. McLeod?

Mrs. Cathy McLeod: No, thank you, Madam Chair.

The Chair: Ms. Murray.

Ms. Joyce Murray (Vancouver Quadra, Lib.): Thank you.

I apologize for missing some of the testimony, but I've been part of this debate for a while. We all know the concerns the provinces have about the absence of...or a thin consultation. For the first time I was going through this and I noticed there was a session where the province of B.C. had someone sitting in for the health minister four years ago. That was obviously an early consultation. There was one other meeting with the medical health officer two years ago. Other than that it was the day before the bill was tabled that the province had a chance to see what was happening at an information session. I think there's clear concern by the provinces.

I'm just wondering, Ms. Gibson, what the probability is of a court challenge to this bill based on jurisdictional issues.

Ms. Elaine Gibson: That's a tough question. I think that involves crystal ball gazing. Quebec in particular has shown an indication of willingness to challenge constitutionally when the federal government has moved into new areas, and this is a relatively new area, at least in certain aspects. It's a brand-new area for the federal government.

I don't know the likelihood of a constitutional challenge. I was actually just raising some concerns should such a challenge happen.

● (1655)

Ms. Joyce Murray: The substance that would be required to justify a constitutional challenge is clearly in front of us, according to your presentation.

Ms. Elaine Gibson: Yes, I would submit that. I would also remind you that at the start of my presentation I referred to the biosecurity and biosafety aspects. The more the act concentrates on biosecurity, the more secure it is on a division-of-powers ground. That applies as well, by the way, to importation of human pathogens and toxins into the country. That's a trade and commerce power.

Ms. Joyce Murray: Dr. Butler-Jones, if there were to be a court challenge, how long would the implementation of these measures be held up? Can you give us an estimate?

Dr. David Butler-Jones: I'll look to the lawyer. The discussions with the provinces and territories and others would suggest that there's no court challenge issue. They just want to make sure their issues are addressed, either in the legislation or the regulations.

Beyond what's there in terms of consultation, there were actually people from B.C., from BCCDC and the ministry, who were part of the commentary as the legislation was developed. There were other contacts with B.C. beyond that.

In terms of a court challenge, I'll leave it to Jane.

Ms. Joyce Murray: I just want to respond to that, though. You may not have heard the beginning of my remarks. From this consultation documentation, we can see that there was one person sitting in for the medical health officer four years ago and one person was in a consultation two years ago. Other than that, British Columbia was at an information session the day before this was tabled, so....

Dr. David Butler-Jones: What you have is a series of consultations. In trying to pull all this information together, in addition, we had people from BCCDC who, as the legislation was being developed, were part of the laboratory reference group in the public health network. They were seeing this at different stages and engaging in discussions. There were also chief medical officers and others.

That's not the purpose of this—

Ms. Joyce Murray: Let's not belabour the point.

What I'm trying to get at is the probability, the chance, that the part of this important work that is widely agreed on will actually be implemented. Is the chance less if you more or less push it through, leaving things to regulation and leaving the provinces with an experience of not having been consulted? In that case, perhaps there would be a greater likelihood that it will not be implemented in the labs. How long might it take to do some redrafting to bring this clarity into the law that many of us and many of the witnesses have been calling for? Would it be two months, one month?

Dr. David Butler-Jones: We're hopeful that perhaps the deliberations of this committee, and any amendments that come, might actually address those concerns in terms of clarity of intent. That is the concern of the province: to make sure that we do what we said we would do in the development of the regulations.

There is a comfort. I've talked to, for example, both deputy ministers, the chief medical officer, the deputy chief medical officer, ADMs, etc., in B.C. They are comfortable with the way forward. I've done this with other provinces as well. I do not anticipate any challenge from the provinces on this legislation. I think everyone I've talked to shares my view, which is that as long as we address things in the way we said we'd address them, they're comfortable with it.

Ms. Joyce Murray: We have a strongly worded letter from British Columbia—

The Chair: I'm sorry, your time is up, but I believe—

Dr. David Butler-Jones: It is a letter to which I responded, and we've been in conversation since the letter.

The Chair: Time is up, but I believe Ms. Gibson had a comment. Please be quick, because we're out of time.

Ms. Elaine Gibson: I wanted to point out that a challenge on the basis of division of powers need not come from one of the provinces. It can come from anyone adversely affected by this act. It could come from a laboratory, for instance.

The Chair: Thank you.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: I would like to address the issue of concerns by the provinces. In addition to Ontario and B.C., I've been in conversation with Manitoba, and there are very strong concerns coming from that province. These concerns are very recent and so have not yet been addressed. In fact, I understand they will be documenting their concerns and forwarding them to...somewhere.

● (1700)

Dr. David Butler-Jones: They have raised concerns. I had breakfast with Joel on Saturday and we talked through all these issues.

Ms. Judy Wasylycia-Leis: The questions and the concerns are all similar for all of us. They're worried about additional costs being imposed on their own governments, duplication of services, unnecessary licensing of labs already regulated by a province, no provision in the bill for equivalency, delays in lab work, and so on.

You're saying now that this is just posturing by the provinces so that they can get their issues addressed in the regulations.

Dr. David Butler-Jones: It's not a matter of posturing. I think these are legitimate questions and concerns. These are positions that they're putting forward. Early on in this process the decision was made that we would deal with them in regulation initially. This committee will deal with items that they might want to include in the act to make the intention, etc., clearer. But what I am saying is that with each of them who I've talked to, each who we've engaged with, the comfort level with the assurances is...but they still want to see those addressed, so they're putting them in writing to ensure that it's on the record.

Ms. Judy Wasylycia-Leis: There are two issues we're dealing with here. One that we're trying to grapple with as a committee is how much do we leave in terms of regulations and when do we thereby abdicate our responsibility as legislators in ensuring accountability of the government. You're saying there will be amendments forthcoming that might address some of these concerns, and we'll wait and see later today or tomorrow, I presume. Secondly, on top of that, the regulations will be sensitive to provincial concerns, for which we have really no control.

I guess we're really hoping that the legislative changes will be satisfactory to the provinces, because that's our only way of measuring reaction and how we go forward.

Dr. David Butler-Jones: Thank you.

As you say, there are two aspects to that. One is whatever comes forward from this committee in terms of amendments, and we'll see. Certainly as an agency we are at your...whatever. Our intent is the agency outcome, and if legislative changes will assist that, that's great.

In terms of the regulations, again, our plan is pretty clear in terms of transparency, and we'll address those things with the provinces, and there'll be many opportunities. I'd be happy—even during the regulatory phase—to have further conversations with the committee, on the wish of the committee, on the intent, the process, and the content of regulations as they develop. I'm certainly quite open to that.

Ms. Judy Wasylycia-Leis: I have one more question, Madam Chair, on something my colleague Carol Hughes has mentioned to me a few times, and it's a legitimate one, and that is what are the cost implications from this bill for the federal government, and what kind of security or inspection regime is envisaged? Is it now budgeted for, or what is the cost associated with additional inspectors?

Dr. Theresa Tam: In terms of the cost to the federal government, which includes security clearance and licence issuance, so there's no cost to the labs, the budget was provided for in Budget 2008. The envelope, if you like, is $37 million with certainly ongoing funding beyond the initial years. The initial years will cost more in terms of the establishment of the program itself—

Dr. David Butler-Jones: Is it $37 million over five years?

Dr. Theresa Tam: Over four years. And then it's ongoing.

Ms. Judy Wasylycia-Leis: Although, as I understood that budget line in the 2008 budget, it was meant to cover the entire surveillance requirements for all proposed legislation, so Bill C-11, Bill C-6, the old Bill C-52 and the old Bill C-51, all of which require significant oversight provisions.

● (1705)

The Chair: Ms. Wasylycia-Leis, we're over time.

Ms. Judy Wasylycia-Leis: So my question is $37 million over four years for all of those provisions might not reflect the accurate cost to make this work.

The Chair: Dr. Tam.

Dr. Theresa Tam: The $37 million is only with respect to this particular legislation.

The Chair: Mr. Brown.

Mr. Patrick Brown (Barrie, CPC): Madam Chair, my first question is to Roland Leitner. I would ask him to comment.

It's well known that risk group 2 pathogens, such as salmonella, listeria, and staphylococcus, occur commonly in the environment, for example, in raw meat in the grocery store. Yet we don't worry to a great extent about that. Could you comment on why we should have a greater concern or anxiety about these micro-organisms in the laboratory?

Mr. Roland Leitner: I have to disagree with you. We do worry about chicken contaminated with salmonella, and certainly the people who get sick do worry about it.

One of the major differences in laboratory environments versus level 2 organisms in the environment is that you take those level 2 organisms, you grow them, you concentrate them, so you have many more organisms per volume. You would also engage in laboratory practices where, for instance, you aerosolize those materials so they become an inhalation hazard. You do all those things in the laboratory environment that you would usually not do at home when you have those materials.

Does that answer your question?

Mr. Patrick Brown: Yes, but maybe you could simplify it a bit. How is the risk grown in a laboratory? Perhaps you could give an example.

Mr. Roland Leitner: Let's distinguish between bacteria and viruses, for instance.

You have different temperature requirements. You have different requirements. You have viruses in special culture flasks that you grow them in. For instance, if you were to encounter HIV, which is a virus, in its natural environment, you would have a very low concentration of those viruses within the blood of a patient. However, if you take HIV, impart it into cells and grow those cells, you would have a much higher concentration of those particular viruses within the same volume. As such, if you were to expose yourself to one drop of human blood infected with HIV, that would be quite different from the number of actual organisms within one drop of tissue culture fluid.

The same goes for bacteria. If you were to grow them, you would have much more per volume than you would have in the natural environment.

Mr. Patrick Brown: I have a question for Raymond Tellier.

Given the fact that you spend much of your professional career working in hospital-associated laboratories, I want to know your thoughts on this. Some have objected to the inclusion of hospital-based laboratories, either diagnostic or research, under the proposed legislation. What are your thoughts on this? With hospitals being under provincial jurisdiction and the fact that individuals work in these hospitals and obviously have a greater risk of catching infectious disease, would it not seem logical to have a different level of government playing a role in the oversight for impartiality purposes?

Dr. Raymond Tellier: Quite frankly, I am not competent to decide on the jurisdiction conflict between provincial and federal governments.

What I can tell you is that from the point of view of the operation of a laboratory, it is highly desirable that proper procedure and regulation be promulgated and enforced to ensure that the necessary laboratory work is conducted safely from the point of view of those who do it and from the point of view of public health considerations, while ensuring that the diagnostic work is done.

What is the line between provincial and federal jurisdictions? I am not a lawyer. I cannot help you there.

Mr. Patrick Brown: In terms of the impartiality aspect of that?

Dr. Raymond Tellier: I'm not sure I follow.

From the point of view of impartiality, pathogenic micro-organisms have been one of humankind's worst enemies since the beginning. And we're all on the same side to make sure we wage the war against those together, with minimal risk.

I'm not sure I understand the question.

● (1710)

Mr. Patrick Brown: I guess a federal regulatory body would have a greater recognition of supervising the provincial operational risk rather than it being more self-governed.

Dr. Raymond Tellier: My initial reaction to that is to make sure that the regulation and authority in the labs is guided by science and that people will have sufficient scientific knowledge about this issue to both promulgate the implementation and make sure it's being followed. I think your greatest guarantee of objectivity there is the scientific know-how of the people involved.

The Chair: Thank you, Mr. Tellier.

Dr. Carrie.

Mr. Colin Carrie: Thank you very much, Madam Chair.

Dr. Butler-Jones, I don't want to put you on the spot, but Madam Murray did bring up the B.C. letter again. And I know Ms. Wasylycia-Leis mentioned that the people that she talked to in Manitoba have some concerns. I know sometimes there's a bit of a disconnect between politicians and the people who work with them. In my own office sometimes people will ask, “Did you do this, or did your staff do it?”, and I don't know if it's done or completed yet and I have to check with them.

But could you reiterate for Ms. Murray—I don't know if she was in the room—was there, let's say, a different communication? You said you had spoken to the B.C. officials since the letter, and I believe you mentioned you'd had breakfast with Manitoba officials. Was there a slight change, once they'd listened to what you had to say and your intent with the way the bill is written? Was there a disconnect there?

Dr. David Butler-Jones: If you don't mind—I mean, it's obviously at the wish of the committee—I think there's a recognition in this that even when you think you've consulted with jurisdictions and had people involved, it's not necessarily the case that everybody talks to everybody in our organization, let alone in theirs. We have been able, I think, to address their concerns as we move forward with both departments in B.C. It was the chief medical officer in Manitoba whom I had breakfast with on Saturday. I had as well a phone conversation with all chief medical officers last week, and there was a whole range of other people that both I and others have had personal conversations with. The fact that not everybody in an organization is aware of the involvement of others in the organization is a reality.

I really don't want to go too far down that road other than to say the conversations are in place. There were conversations in place, but not everybody was communicated with in the way we had hoped, on all sides, and I think there are some lessons in that for us. But on the substantive issues of whether there are issues being addressed and whether they feel they can be addressed, I would say, yes, and we are committed to making that happen.

Mr. Colin Carrie: Thank you very much.

You also mentioned earlier some of these lists. It was mentioned that polio was on, then polio was off. You said you had listened to stakeholders before, and that's why the lists were changed.

In your opinion, is it easier to have a tougher list or a lighter list, or does it really matter?

Dr. David Butler-Jones: Again, what's attached to the act is for illustrative purposes only; it is not intended to represent what will be regulated.

Ms. Jane Allain: Can I tackle this?

Dr. David Butler-Jones: You can do the legal definition of it, and then I'll say how we're going to use it.

Ms. Jane Allain: Essentially, there are two things that you have to look at when you look at the statute. You have to look at the definitions that are in the risk groups—risk group 2, risk group 3, risk group 4 definitions—which is what the intention is, and they fall into the different categories. These are definitions that are in the biological safety guidelines and they're definitions that the scientific community have over the years developed and refined. They are definitions that are acceptable.

On that, there is, as Dr. Butler-Jones has indicated, the list of attached schedules and toxins. The schedules, as they're listed, are mirrored back to those risk groups. So it's not an exhaustive list; it's not every one enumerated. You have to look at both the definition and the list.

For the prohibited substances that no one can have, as in schedule 5, that is a closed list, and that is only for smallpox.

● (1715)

Dr. David Butler-Jones: Then what will happen in the regulations, where you specify which level of regulation requirement is for which bugs, will require fairly extensive scientific input. For example, level 2 would not require security clearance. Not all level 3 would require a security clearance. Clearly, for people working with bioterrorist agents, they would likely end up requiring that. But clearly not all level 3 agents are a security concern in that same way. But we need to go through the consultations on the specifics.

The other thing is that times change. The reason for having the regulations as opposed to the act is that should new bioterrorist agents be developed, or other things, you need the ability to adapt the regulations accordingly.

Mr. Colin Carrie: Thank you very much.

The Chair: The bells are going now, so I guess we'll have to adjourn to vote. We have a notice of motion from Dr. Duncan that we'll have to deal with next day.

We want to thank you so much for coming today.

Ms. Murray.

Ms. Joyce Murray: I'd like to propose something for the next meeting. It's not with respect to the panel. I suggest we not go through clause by clause until after Easter, because there may be some changes coming from the department that we will need to have time to look at. We'll need time to go back to our provinces and the medical officers, and so on, to ask whether this substantively addresses their concerns. We cannot do that and do clause-by-clause on Thursday. So I propose we put that after Easter and start working on our study.

The Chair: We have to decide quickly.

We had planned to go clause by clause on Thursday. The suggestion is that we wait until after Easter.

Dr. Carrie.

Mr. Colin Carrie: I believe there are some meetings later on today and tomorrow where discussions could be made on potential amendments. I don't feel that we need to wait until after Easter. If we put it off until Tuesday, that will give us a lot of time. You'll be able to be in touch with people who may have differing opinions. Then we can get on with the clause-by-clause and the actual amendments. You'll still have the weekend and everything to phone people.

The Chair: Dr. Bennett.

Hon. Carolyn Bennett: Rather than phoning people, I would like the researchers to choose the witnesses who seem to have the most difficulty with the bill to see if they are available to come back on Thursday to let us know whether they think the amendments deal appropriately with it. If that's not possible, they should come on Tuesday, but they should be provided with the government amendments before they come back.

The Chair: Dr. Carrie.

Mr. Colin Carrie: Can I make a compromise, Dr. Bennett? What if we try to get those people back on Thursday, and if the officials can come back on Thursday we can have a balanced explanation. Sometimes as legislators we do not have the expertise you have. Would you be okay with that, Dr. Bennett? Then we can schedule clause-by-clause for Tuesday, because it should be handled.

The Chair: We'll do that. We'll continue on Thursday then.

We'll do the motion on Thursday as well.

The meeting is adjourned.

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