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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1535)

[*English*]

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

You will notice that there are two motions being handed out. We will go very quickly to Dr. Duncan's notice of motion. It will take just a couple of minutes.

First of all, Dr. Duncan, you will have to have the permission of the committee to change your motion. Then we will do a yes or no on it. You have the floor.

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

Good afternoon, everyone.

We had previously discussed neurological disorders. My initial motion in that regard was very ambitious as drafted. I've decided to reduce it a bit. I would begin by asking your permission to change that motion.

Some hon. members: Agreed.

The Chair: Go right ahead, Dr. Duncan.

Ms. Kirsty Duncan: Thank you.

At the dinner with the minister, we had a long discussion about neurological disorders and the lack of attention and money they receive here in Canada. I am hoping that we could strike a subcommittee to look at neurological disease in Canada, particularly autism, MS, ALS, Parkinson's disease, and Alzheimer's; to look at new technologies, which are yielding positive results in other parts of the world; and to investigate the possibility of bringing successful therapies here.

The Chair: What we're going to do very quickly is look over the motion. I'll just read it out, as follows:

> That the Health Committee should strike a sub-committee or have a conference to examine the burden of neurological disease in Canada; explore results of clinical trials and experimental technologies, which are yielding positive results here in Canada and internationally; and investigate the possibility of bringing successful therapies to Canada.

We can discuss this at a further point. Are we in agreement—by a show of hands—that we should either have a subcommittee or a conference at some point in time to take a look at this particular condition?

Some hon. members: Agreed.

The Chair: That's passed.

With your permission, Dr. Duncan—I know you have to get to the House to speak—what we'll do is discuss this at one of the subsequent meetings as to whether or not it should be a conference or a subcommittee.

Ms. Kirsty Duncan: Thank you, Madam Chair, and thank you to the committee.

The Chair: You're so welcome.

Welcome to our witnesses. Once again we are having testimony in terms of Bill C-11. We have the Public Health Agency of Canada, the Institut national de la recherche scientifique, Laval University, McGill University, and the McLaughlin-Rotman Centre for Global Health.

Without further ado, we will ask one person from each organization to give a 10-minute presentation, if they so choose. We will start with the Public Health Agency of Canada.

Who would like to make this presentation?

Dr. David Butler-Jones.

Dr. David Butler-Jones (Chief Public Health Officer, Public Health Agency of Canada): Thank you once again for the opportunity to further discuss this critical piece of legislation with the committee and witnesses.

Obviously l've listened with interest to the comments presented at standing committee over the last few weeks and understand the importance and the relevance of the views that stakeholders have brought forward. It's in everybody's interest to have the best legislation possible. I have indicated that I am open to discussions on how the bill could be strengthened.

The perspectives that have been presented by a variety of witnesses show the value of what we are trying to achieve and the importance people place on getting it right. Human pathogens are dangerous, as they are capable of causing disease and death. For that reason, we have to be diligent in creating a legislative base that balances biosafety with not restricting scientific advancement—providing assurances, at the same time, to the Canadian public and our international partners that Canada takes the biosecurity imperative seriously.

In order to achieve that much needed balance, I want to reinforce that we are committed to continuing this dialogue and to working closely with our partners and stakeholders. We will develop a program and regulatory framework that responds to the needs and the interest of the scientific community while improving biosecurity and biosafety.

[*Translation*]

In terms of this discussion, there are some questions that have been raised that I want to address directly.

[*English*]

First, why do we need this legislation now? Why not take more time to consult on the legislation before the in-depth consultations on the program and regulations?

As Chief Public Health Officer, I have recommended that we develop legislation that establishes a safety and security regime for all laboratories to protect the health and safety of the public.

Going forward, consultations will help determine what this regime will look like. We are committed to framing these consultations in a way that will best suit the needs of provinces and territories and our stakeholders and partners in the academic and hospital communities.

All of our international counterparts have had similar legislation in place for years. Although Canada has not experienced a large intentional or unintentional release of a dangerous agent, this is not a reason for complacency. We have had some close calls in this country.

[*Translation*]

We have had some close calls in this country.

[*English*]

As an example, in April of 2005, a facility in Canada imported a live virus sample under a risk group 2 permit. Upon laboratory analysis, it was realized that the material was contaminated with a risk group 3 human pathogen, an influenza H2N2 strain.

Once the contamination was confirmed, the Public Health Agency of Canada's importation office, the Office of Laboratory Security, in consultation with the WHO, the U.S. Centers for Disease Control, and the provincial health ministries contacted the supplier of the material and all facilities in Canada that had been issued a permit for the same panel and advised them of corrective action.

● (1540)

[*Translation*]

It was only because the material was imported that the federal government was able to track who had the affected materials.

[*English*]

Should this situation happen today in Canada with a domestically produced product, there would be no authority or ability to track materials and advise affected parties of corrective action. This could result in a biosafety and biosecurity risk. Canadians would have had no immunity to this virus, possibly creating the conditions for the next influenza pandemic.

If something like this were to happen, Canadians would demand and have a right to an explanation for why we did not and could not protect them. There is an opportunity, through this bill, to make Canada safer.

The second important question that has been raised has focused on speculation around the potential cost of the program and the regulatory framework and the perception that these costs will be onerous. We have anticipated and listened to the concerns about cost. This issue is front and centre for us in terms of the development of the associated program and the regulatory framework, and we'll continue to work towards achieving that goal to develop a cost-efficient and effective program.

As witnesses such as Mr. Leitner, who have implemented or are implementing biosafety and other regulatory activities, have indicated, neither the impact nor the cost of these activities has been onerous. However, the cost of inaction in terms of dollars, our credibility, and human life is potentially far greater.

As the committee is aware, other concerns are identified and addressed in the draft regulatory framework and through our commitments on the process of consultation.

[*Translation*]

Finally, I want to address the question of our willingness and commitment to listening to our partners and working together.

[*English*]

We have taken and continue to take action to address concerns that our partners have raised. These have been excellent, productive discussions. Our partners have told us that they are comfortable with the actions we are taking, and I am optimistic that we are going to move forward together.

Specifically, I have been in direct contact with the Province of British Columbia, including Mr. Gordon Macatee, deputy minister for the B.C. Ministry of Health Services, Grant Main, deputy minister, and Andrew Hazlewood, assistant deputy minister, as well as Dr. Perry Kendall, B.C. Provincial Health Officer, and others.

I've spoken with Ms. Arlene Wilgosh, deputy minister in Manitoba and provincial-territorial co-chair of the conference of FPT deputy ministers.

Further, I've spoken with Dr. Vivek Goel, president and chief executive officer of the Ontario Agency for Health Protection and Promotion, Mr. Ron Sapsford, deputy minister of the Ontario Ministry of Health and Long-Term Care, and Dr. David Williams, acting Chief Medical Officer of Health for Ontario.

We have had a follow-up conference call with the Council of Chief Medical Officers of Health and the Canadian Public Health Laboratory Network, and further discussion will continue over the coming weeks.

Finally, I've also spoken with the Privacy Commissioner, Ms. Jennifer Stoddart, and Dr. Lorne Babiuk, from the University of Alberta, on behalf of the group of university vice-presidents of research.

Beyond my personal interventions, there have also been a number of other discussions by officials with provincial, territorial, and academic partners, as well as with the Office of the Privacy Commissioner.

We continue to work very hard with these partners in order to ensure all relevant issues are addressed, and we are committed to them over the long term. I believe that as a result of these interventions there is broader understanding of what the government is trying to achieve through this bill. In addition, I have heard their messages regarding various ways to improve the overall intent of the bill and its future regulations—discussions that have been very fruitful and will continue to be as we go forward.

Ultimately, our partnerships are not only about the development of legislation or regulation, but about the fundamental collaboration and cooperation required to continue to protect the health and safety of Canadians in all respects.

[*Translation*]

Thank you.

[*English*]

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

We'd now like to go to Mr. Descoteaux.

[*Translation*]

Dr. Albert Descoteaux (Professor, Institut Armand-Frappier, Institut national de la recherche scientifique): Thank you again for giving me the opportunity to express some fears or concerns about Bill C-11. I would like to take the opportunity to raise a matter that went unnoticed last time: bacterial toxins.

The CDC in the United States consider two or three toxins to be really dangerous. Most of the toxins on the list are very important research tools. We use them to study how cells work in cancer, in neurology and in immunology. Examples are the cholera toxin, the *Clostridium botulinum* toxin and the *pertussis* toxin. I am afraid that, if access to these toxins becomes too complicated, it could be very detrimental to research in cellular biology.

I also have some concerns about HIV. In the bill, HIV is classed at level 3. But it is a fact that several research groups and research networks in Canada have established sample banks, with samples taken from thousands of patients infected with HIV. These banks are invaluable for HIV research. One example is the Réseau SIDA et Maladies infectieuses, run by the Fonds de la recherche en santé du Québec. Members of that network have access to various banks of samples: from patients with primary infection, from slow progressors, and from patients infected with HIV and the hepatitis C virus.

Since HIV is now in containment group 3, I seriously wonder about the impact that Bill C-11 could have on the access to, and use of, these thousands of samples by qualified researchers. We can only imagine the bureaucracy and the permits needed for laboratories to exchange strains. And it is not just networks. Hundreds of professors and students need to handle and use these lines. We run the risk of setting up a huge logistical challenge, not to mention the impact on AIDS research.

I have to point out that these sample banks were established with grants from federal and provincial organizations. Bill C-11 would destroy all the financial commitments from government in the fight against AIDS. Paradoxically, that remains a federal government priority. I would really like that considered when you decide your position on Bill C-11.

There has also been talk of micro-organisms potentially being used for malicious purposes like bioterrorism. I have given Mr. Etoka a list from the Centers for Disease Control's website in Atlanta. The list is in English only and has not been circulated to everyone, but you can easily get it. It is a list of agents that can be used in bioterrorism.

The first thing we see is that the list of micro-organisms that are considered very dangerous is very short. There are six: anthrax, botulism, plague, smallpox, tularemia and the hemorrhagic fevers.

The second thing we notice is that these micro-organisms all belong to confinement groups 3 and 4, except smallpox, which is in group 5.

The third thing is this. In the list of micro-organisms that the CDC consider less dangerous because of their moderate morbidity and low mortality but that could still be potentially used for bioterrorism, some are in confinement group 2, like salmonella, some strains of E. coli, like 0157:H7, *vibrio cholerae* and *cryptosporidium*. In general, these are the micro-organisms most often responsible for food poisoning or contaminated water. Poisonings and contaminations of that kind are often due to poor hygiene practices or negligence on the part of the people in charge of water quality.

After I appeared here two weeks ago, I have had discussions with my colleagues and I have thought about the matter some more.

● (1545)

I would like to end with a recommendation. If the goal of lawmakers is to promote public health and safety in the area of micro-organisms and to protect Canadians from potential bioterrorist attacks, Bill C-11is not the solution. I feel that the bill could well create havoc by establishing a repressive system that lumps all micro-organisms together, whereas the vast majority of them pose no problem at all for people's health and safety. My recommendation is that lawmakers and the Public Health Agency of Canada concentrate on the few micro-organisms that potentially can be used maliciously and put in place appropriate measures for them.

Thank you for your attention. I will be pleased to answer your questions.

[*English*]

The Chair: Thank you very much.

We'll now go to Monsieur Ouellette.

Professor Marc Ouellette (Professor, Laval University): I'll be very brief.

● (1550)

[*Translation*]

I am here mostly to answer questions. We have already given our presentations. I will just say that the four of us had only 24 hours' notice, and we are here.

[*English*]

because it's very important for us. This is the bottom line. It is very important. We hope this bill will be useful and acceptable to all. That's it.

The Chair: Is that your presentation? It's wonderful. Do you have anything else to say?

Prof. Marc Ouellette: No. I'm here to answer questions.

The Chair: Well, I think a lot of us are very anxious to ask some. Thank you.

We will now go to Mr. Matlashewski.

Professor Greg Matlashewski (Department of Microbiology and Immunology, McGill University): I'll also be brief, because I know you've heard a lot of different discussions.

I read the comments that you heard recently from Elaine Gibson, and I would like to support them. The most important thing is to get this bill right so that everybody concurs that it's the right thing to do.

I think it's really important that the regulations be included within this bill, because otherwise the bill is an empty shell. You're having a law in which the regulations can come and go and change from one government to another government. The bill will mean very little without real regulations within it, as far as I'm concerned. I think there's a real danger in passing this bill without having the regulations, because I've seen some of the amendments, and these amendments have not changed the bill substantially. If these kinds of amendments are what is envisaged for the regulations, then I think there are going to be some real problems in the future.

I would like to slow everything down and go back and put the regulations into the bill. This way we'll have a bill that will serve Parliament better and serve Canadians better.

The Chair: Thank you very much.

We'll now go to Mr. Singer, please.

Dr. Peter Singer (Director and Professor of Medicine, University Health Network and University of Toronto, McLaughlin-Rotman Centre for Global Health): Thank you, and thanks for the invitation back. I'll also be brief, because I understand the primary purpose is to respond to questions.

The first point I'd like to make is that I very strongly support the need for legislation on this matter of pathogen security. I actually think there is some urgency to passing the right legislation. For example, a U.S. congressional committee late last year found that it was more likely than not that there would be a weapons of mass destruction attack somewhere in the world by 2013, and a biological one was more likely than a nuclear one. So we don't want to drag this out for months and months and months.

Secondly, having said that, I'd like to focus my remarks by really zeroing down on the question of the inclusion of level 2 pathogens in this bill. I would like to tentatively put forward a position or pose a question—maybe even do this in a type of question-and-answer format, since we have this great opportunity of being here with Dr. Butler-Jones and his colleagues, whom I have a great degree of esteem for—and maybe Dr. Butler-Jones and his colleagues would be able to respond.

Wouldn't this be a better bill if level 2 pathogens were just taken out of it? I want to advance four lines of argument around this supposition.

First, I didn't hear in any of the testimony real evidence and proof that the inclusion of level 2 pathogens makes us considerably safer. You'll remember that my testimony last time had to do with the point that pathogen security does not equal biosecurity, especially when you're talking about level 2 pathogens. I would just like to hear more of the case that the inclusion of level 2 pathogens is actually a very, very significant benefit.

My second line of argument is that if the criminal penalties were reduced for level 2 pathogens—and that would be an obvious move to make in amendments—you're still going to be left with criminal penalties. And that's a very, very significant thing for scientists. In a nutshell, you could get into a situation where sloppy record-keeping on the part of a scientist in a relatively low risk, level 2 lab, or by a student or faculty member—though the faculty member would probably be accountable in this case, or the university—could leave someone with a criminal conviction. Even if there were no fine or jail term, that person couldn't then travel to the United States. That's a very serious use of the criminal law in a relatively low-risk situation.

The third line of argument I would like to advance, just in this hypothetical case of it being a better law if you took level 2 pathogens out of it, is the comparison with the U.S. In the days since I heard from the clerk, I've been in touch with some biosecurity colleagues in the U.S. I asked them about regulation of level 2 pathogens in the U.S. It turns out that what's criminally and federally legislated in the U.S. is this U.S. list of select agents and toxins. If you read the stuff on the U.S. select agents list, it correlates mostly with what's in schedules 3, 4, and 5 in Bill C-11, I think, exclusively—but I haven't done this in detail. Maybe there's one that's in level 2. But to my knowledge—and I would be interested in the response from PHAC colleagues—I didn't find any level 2 pathogens from Bill C-11 on the U.S. select agents list. Everything else is regulated, but not federally and not criminally, in the United States. So I left this list wondering if a somewhat bioterrorism-obsessed country like the United States, which passed legislation in the wake of an actual attack, doesn't even regulate level 2 pathogens in a criminal and federal way, why would Canada do that?

Finally—and this is an issue of leaving the matter for regulation, and again focusing just on level 2 pathogens—imagine you're regulating level 2 labs across the country. Imagine the horrendous, but not impossible, scenario of there actually being an attack. What will the cabinet do to those regulations the day after the attack, when there's considerable pressure to change them? Do you really want a situation where the level 2 pathogens, which can be relatively low risk, are in a piece of legislation, with regulatory provisions for them, and cabinet can change those regulations in a climate of fear after an attack, and do so without going back to Parliament?

● (1555)

That's why it's the day-after-the-attack scenario that I want you to think through.

I'm perfectly comfortable if on the day after an attack—God forbid that it should occur—cabinet does something with level 3 or level 4 labs. Those have very serious pathogens. However, at U of T, for instance, there are somewhere between one and three level 3 labs; there are hundreds of level 2 labs. They are relatively low risk and much larger in number. Do you really want to be in that situation of a climate of fear in which something can happen?

In summary, the legislation could definitely be made better by amending it to change penalties, security clearances, etc., related to level 2 pathogens, but I'd love to hear a response to the idea that this would be a better bill if you excluded them totally. You could pass the bill very quickly by doing so, and I believe this is a good bill and should be passed very quickly. Again, are the benefits really so great for level 2? Criminal penalties are serious, and I'll mention again the U.S. comparison the day after the attack.

In closing, I'd like to say that we should not just leave consideration of level 2 pathogens and the security issues around level 2 pathogens. That's exactly the sort of question that could be referred, as I mentioned in my earlier remarks, to the Council of Canadian Academies, the Canadian Academy of Health Sciences, or the Canadian Academy of Engineering. I would love to see an assessment by the academies of the way of dealing with level 2 pathogens or labs that would make this country most secure. I can't guarantee they'd immediately get to the legislation that would answer that question. They might, and if they did in a year or two, this legislation could be amended, but there are so many other things that could be done, including dealing with issues around next-generation threats and the web of protection I mentioned last time.

I feel that would be a better way to deal with level 2 pathogens, and then the government would be acting extremely responsibly. It would have closed this hole on regulation of level 3 and level 4, which is desperately needed—and I agree with this bill and the urgency for it—and it would not have left level 2 pathogens alone. It would actually be acting in a very responsible way in sorting out the best way to regulate them, and it would give the best advice to government, which is the role of the Council of Canadian Academies, on how to make this country more secure with respect to level 2 pathogens.

Thank you very much. I just put some probes there for my friend and colleague David Butler-Jones, and I very much look forward to the give and take that this panel allows.

The Chair: Thank you, Dr. Singer.

We'll now go into the first round, a seven-minute round. We have seven minutes for the questions and answers. We'll start with Dr. Bennett.

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

I think we do want to see a to-and-fro in terms of the improvements that have been suggested by the government amendments, but also in terms of the lingering concerns, particularly those related to regulations.

I noticed that in his letter, Dr. Goel says that as much as he welcomes the amendments, any further means of ensuring transparency on the process around the development and approval of these regulations would be helpful. I would like to know from the Public Health Agency of Canada whether there's a way that process could be committed to within the bill. Then I would also like them to speak to the NDP amendment around bringing the regulations back to committee.

I wasn't sure whether the officials had seen the comments in response to the amendments by Elaine Gibson, because you wouldn't have seen her original testimony when the amendments were drafted. I will read it in to the record:

> The Bill is improved in that the amendments clarify that there are different standards for Risk Group 2 in terms of security screening, regulations, and penalties. However, licenses will still be required for those using Risk Group 2 pathogens/toxins, it appears.
>
> It addresses only minimally my concern that so much of the workings of this Act are being left over to be included in regulations as opposed to in the legislation itself. This is significant and ties in to concerns of the scientific community.
>
> It doesn't address my concern regarding the constitutionality of including Risk Group 2 in that this appears more regulatory than criminal, and if so it may fall under provincial property and civil rights powers and not federal power over criminal law.
>
> A number of concerns regarding privacy voiced [by] both the federal Privacy Commissioner and me have not been addressed—need for information to be in as de-identified a form as required for the purpose; need for adding the standard of 'reasonably required' in many of the more intrusive search and seizure powers. Also the Privacy Commissioner argued that a Privacy Impact Assessment needs to be conducted.

Could you respond to not only what the witnesses have said, but also to these concerns from two of the previous detractors?

● (1600)

The Chair: Dr. Butler, would you like to take that question?

Dr. David Butler-Jones: Sure. Hopefully I'll capture it all. I'll turn to Theresa.

Perhaps I'll start with the last first. As I said, I've spoken to the Privacy Commissioner. Theresa met with her office yesterday. It's not about personally identified information; it is about the regulation of the materials. They're looking forward to it, and it is appropriate for the privacy assessment to take place when we're forming the program architecture for that, and their office is quite comfortable with that. So I think we've addressed their concerns as they are.

In terms of whether there should be an amendment come forward that brings it back to committee, for example, as an agency we have no problem with that. I've already committed, with or without it being in the legislation, that we are quite comfortable coming back to committee if it's the wish of the committee. As I said before, that's a legislative option.

In terms of the part I think you may have been alluding, regarding Peter's question about why it's level 2, I guess there are a number of reasons we include it. We already regulate level 2 now. It's in the regulations for import and export, and it's in the regulations for transport. Half the labs in the country are already under this regime.

I made reference to H2N2. The agency recognized it and was able to track it down because of the regulatory regime about import and export. If it were domestic, we would not have been able to do that. It came from the States. It was sent around the world as a sort of test kit, and H2N2 was put in there by mistake. Could you imagine the implications of the Americans having started the next pandemic unintentionally but intentionally in the sense of having distributed material?

We've also had instances now of abandoned laboratories and fridges full of materials, and the province not being in a position to actually compel information as to what's in there and who it's been sent to. So we need a minimal regulatory regime for level 2 to ensure that we have the ability to find out what's there and what's been sent where. I'm concerned about it from a public health standpoint as well as for consistency with the import and export. For most labs it should not mean much, if any, additional work.

Certainly with the concerns that were raised around HIV, etc.... Currently transport of level 2 pathogens requires forms to be filled out. The actual regime, if you look at the regulatory framework, is meant to minimize any efforts. It's really more focused on that if there's a problem, we will have the power or authority to actually address these issues.

Madame, was there another question that I've missed? I'm sorry.

● (1605)

The Chair: There was the constitutionality.

Dr. David Butler-Jones: I'll turn it to the expert.

Ms. Jane Allain (General Counsel, Legal Services, Public Health Agency of Canada): I don't know if I would use that term.

As a rule, a law can be considered as falling within Parliament's jurisdiction over criminal law. As I mentioned before, when there's a prohibition accompanied by a sanction, and the prohibition is targeted towards a legitimate public purpose or interest, the criminal law purposes can be to address the public peace and order, security, environmental protection, or health and safety. Those are just examples. They're not the exclusive areas of criminal law.

It's a broad area of jurisdiction, and it has a broad range of legislation that has been enacted under that head of power already. The criminal law is not frozen in time, nor is it confined to a fixed area of activity. The courts have told us over many years that Parliament can respond to new realities, and Parliament has the power to decide what is criminal and what is not, and what new crimes...what is needed to respond to changes in social situations.

The simple assessment that the courts ask Parliament to make is whether there's a reasoned apprehension of harm.

The criminal law part doesn't have to create total and direct prohibitions. It can actually use indirect goals to achieve the criminal law purpose. Again, it can pass purely preventive legislation criminalizing only secondary aspects of activities such as the regulation of tobacco.

We have many examples of criminal law legislation that have contained valid exemptions and the conduct and control of certain activities. The Supreme Court of Canada has told us over many times and in various legislation, whether it's the Food and Drugs Act, the Hazardous Products Act, the Controlled Drugs and Substances Act, or the Firearms Act, that these are legitimate regimes, and they can actually be accompanied by very detailed regulations. But that does not make it a non-criminal law. It's still a criminal law. These highly detailed requirements and standards can be set out in the regulations, and that is essentially the regime that you have currently under the Food and Drugs Act.

So this is the type of model legislation that is envisioned under Bill C-11, and it's to establish, as many witnesses have said, a safety and regulatory regime, a safety and security regime to protect the health and safety of Canadians against the risks and harms posed by the use, possession, transfer, disposition, or destruction of human pathogens and toxins. So we believe it's on very solid constitutional grounds.

The Chair: Thank you, Ms. Allain.

We'll now go to Mr. Dufour.

[*Translation*]

Mr. Nicolas Dufour (Repentigny, BQ): Thank you very much, Madam Chair.

Thank you for being here. Your statements were short, but you were able to point out some of your fears about the proposed amendments in the Public Health Agency of Canada's document. You say that you were advised 24 hours in advance. So I assume that you received their information 24 hours in advance.

Could you tell me if the government's proposed amendments change the bill significantly? Do they give you that impression?

Prof. Marc Ouellette: My statement was short because I was told that this was mostly a time for discussion. So I can give you a little longer answer now.

Yes, we did receive the Public Health Agency of Canada's amendments 24 hours in advance. I have to say that the amendments are significant in their way. But they are cosmetic given that the experts who have come to testify, from a legal, scientific or medical perspective, all agree: the bill would be perfect for levels 3 and 4.

However, when you start to try to bring in level 2, things get a little more complicated. Even at level 3, to some extent. Our colleague Dr. Descoteaux mentioned HIV, which is not presently classed at level 3, because it is not aerosol-transmitted, but at level 2.8 or 2.9. Without going into technical details, according to the guidelines, HIV is not the same thing as tuberculosis or anthrax, for example. Do not forget that the HIV lobby is very strong and, if ever HIV were made a level 3 pathogen, people would be up in arms.

That said, we do not think that the bill should exclude level 2 entirely. Health Canada can attest to the fact that we do apply for licences. I gave you a document...

● (1610)

[*English*]

of about 22 pages that we have to fill out in order to be able to import strains from all around the world. So now there's a new amendment, and under the amendment we will also now need something in order to export. We will have to do due diligence on the people to whom we're going to send the strains. This is something new for us. It was not in the bill itself, but it was in the amendment.

So how do we do the due diligence on the people to whom we will send the strains? Is it enough that they be a university professor of biosafety? Or do we have to do a criminal check? I don't think it will be that way, but this is new for us.

To export things now, we also have to ask permission. They need their import permit for what we're sending.

Since we were coming here today, we received a number of documents from Health Canada, which we very much appreciated. I didn't know which document it was, so I read the first one, and I thought it was pretty bad. It was actually Bill C-11, and how it was explained to people.

I said there are new things here, and some are good and some are not that good. Those were the regulations. So why not put the regulations into the bill and then everybody will understand what the goal is?

[*Translation*]

Level 2 pathogens constitute 95% of the activity. Level 3 is pretty much 5% because there is only one laboratory in Canada that handles level 4, in Winnipeg. We all agree, when we are working with diseases that are potentially very dangerous, there has to be an extreme level of security.

Level 2 pathogens are the bread and butter of people doing research. We already have regulations. I mentioned that, in order to get money, we have to get approval from regulatory bodies, university bodies, institutional bodies and the bodies that are going to give us the money. Then, we have to apply for licences from Health Canada.

[*English*]

When we're asking for a strain for importation, we need Health Canada, but we also need CFIA, the Canadian Food Inspection Agency. Do the governments talk to each other, or will there be another set of regulations for CFIA,because it's not possible for us to import something only from the Public Health Agency? We also ask, will there be two types of regulations, one for Health Canada and one for CFIA?

In conclusion,

[*Translation*]

...level 2 pathogens should be controlled as they are now, and I feel that it works very well. It is a system that has been institutionalized for a long time. For pathogens in levels 3 and 4, the dangerous ones like anthrax, the bill should go into effect. We will have to see about HIV. For level 2, we still have concerns.

Mr. Nicolas Dufour: Do you feel the same way, Dr. Descoteaux?

Dr. Albert Descoteaux: Yes; I received a copy of the proposed amendments after the witnesses were heard. It does not seem that the advice about excluding level 2 micro-organisms has been taken into consideration. You have reduced the fine from $250,000 to $50,000. Thank you very much, that is a great relief. It means that, the first time a student in my laboratory commits an offence, or I do, we have $200,000 less to pay.

Something else continues to bother me. As Marc mentioned, 95% of the people in Canada are working with level 2 micro-organisms that pose no danger to health. But the words that frequently come up are *penalty, offence, contravention.* Microbiology researchers and students are being treated like potential criminals. I have a problem with that. I do not think that we should be treated like criminals. We are working to understand infectious diseases better, so that we can diagnose and treat them. I see no reason why we should be treated like potential criminals. That is the problem.

● (1615)

[*English*]

The Chair: Thank you, Dr. Descoteaux.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): I'm tempted to ask whether you've read Bill C-9, the bill that we just passed yesterday on the transportation of dangerous goods, and see whether there's also some conflict between Bill C-11 and Bill C-9. But I won't go there right now.

I sense a less than enthusiastic response from our scientific research community to these amendments.

I want to start by asking Mr. Singer what he thought of Mr. Butler-Jones' response to his suggestion of separating out all level 2s.

Dr. Peter Singer: I thought, as usual, there was a lot of cogency in what David Butler-Jones said. He gave an actual scenario that did establish some benefit in regulating level 2s. What I would like to go back to in the back and forth with him is that it was almost that an implicit assumption was that you're regulating them through Bill C-11, where they're completely unregulated. So even taking that scenario, for instance, thinking about the institutional regulatory frameworks, the provincial regulatory frameworks, all the various other regulatory frameworks, which are less intrusive than the criminal law, could not one have achieved, in that or similar cases, a similar result? That's one question I would ask back.

Secondly, for me, this U.S. comparison is very revealing. I'd really appreciate an answer to the question, if the United States, in the wake of an actual anthrax attack, passed legislation that criminalizes stuff that looks like level 3 and level 4, but level 2 pathogens, by and large, as I understand it, in the United States are dealt with through CDC guidelines, and so on, not criminal law, why does Canada need to criminalize more of the scope of pathogens than the United States does?

I also made a point about criminal law being important, even without penalties for scientists, and the day after the attack, which David may or may not want to respond to.

But really, these are the two things I'd love to hear in this back and forth.

One, wouldn't all the institutional regulation, provincial regulation, etc., cover scenarios like the one you described? Maybe not. That would be important to hear.

Secondly, in terms of the U.S. comparison, why should we criminalize more pathogens and more laboratories than the bioterrorism-stricken and more obsessed United States does, where we know that the Patriot Act and select agent rules have already had some unintended consequences, such as in the Butler case—not Butler-Jones, but Butler—that you mentioned last time?

The Chair: Go ahead.

Dr. David Butler-Jones: I guess there are a couple of things, and then I'll let Jane speak to the legal aspect more specifically.

But particularly as it relates to the ability or the limitations around the changing of the regulations and the development of the regulations—and it's not about criminalizing labs or scientists. In the 15 years that half the labs in the country have been importing and exporting under regulations, with penalties potentially including jail time, it has never been used. It's never needed to be used, because again, it's a collaborative, cooperative kind of process.

As far as the issue of whether the existing regimes can address it goes, I've just given you two examples of where they would not have addressed it, and could not address it, even in a province that has an extensive regulatory regime around laboratories. It's outside of their regime.

I'm really not worried about academic labs and university labs. But there are a number of other labs, and nobody's really sure that they're out there and what they're doing, or what they have in their fridges and how they're doing it.

When provinces do regulate, by and large it's on occupational health and safety and on laboratory standards, not on public safety.

So any regime that we begin, both for what bugs are in and out and for the level of regulation, is really for consultation with scientists and others regarding what makes sense. It doesn't make sense to have tuberculosis at the same standard as others like anthrax, for instance. That will be addressed in the development of the regulations.

I think I'll leave it at that and turn it over to Jane, to talk in terms of the regulatory powers, and so on.

● (1620)

Ms. Jane Allain: Do you mean in terms of how you establish regulations?

Dr. David Butler-Jones: I mean once the regulations are established and the process of notification and so on that we would be following.... That would not, in terms of your scenario, Peter, about the day after...and suddenly we're going to do something.

Ms. Jane Allain: Right.

Ms. Judy Wasylycia-Leis: Could you also address, though, the issue of the difference between the U.S. system and this one, and whether or not level 2 is part of the Patriot Act, in terms of criminalization?

Dr. David Butler-Jones: I'll ask Theresa.

Ms. Theresa Tam (Director General, Centre for Emergency Preparedness and Response, Infectious Disease and Emergency Preparedness Branch, Public Health Agency of Canada): I could try to answer this.

The made-in-Canada solution, this Bill C-11 and the program thereafter, is to establish biosafety and biosecurity and to protect Canadians from pathogens. It's important for us to know who holds pathogens, whether they are in risk group 2 or not. All we want to do is to know that when institutions, organizations, and laboratories hold pathogens, we actually know who these people are and that they are handling things in a safe manner, according to laboratory biosafety guidelines.

Now, for risk group 2, for the most part, we are not asking for security clearance, because we do not believe they are a bioterrorism risk.

The type of risk group 3 pathogens and all the risk group 4 pathogens, or specific toxins, we would like to discuss in the regulatory development are probably similar to those on the U.S. list—I'm not saying the list would match, but they would probably have a similar kind of approach, so that the select agent rule is about biosecurity, bioterrorism.

This bill is establishing a single, uniform standard for safety in Canada, and that's important to Canadians. Every Canadian will want to know that we actually know where laboratories are and who holds pathogens, and that whoever is holding the pathogens is handling them in a safe manner.

Ms. Judy Wasylycia-Leis: Well, why doesn't the United States put their level 2s under a criminal code framework?

Ms. Theresa Tam: I can't comment on why the United States did what they did, but they certainly have a bioterrorism focus. We are promoting a biosafety regime that's uniform across Canada.

As Dr. Butler-Jones said, our human pathogen importation regulation actually has a maximum of up to three months of jail time as well. Again, that has never been utilized. If it's a repeat offence, if we've done a lot of work with the lab and they still didn't do anything and they were not diligent and abandoned their pathogens, etc.... Those extreme circumstances, I imagine, are exceedingly rare and we wouldn't really be going towards them. But that is still in the existing human pathogen importation regulations.

The Chair: Thank you, Dr. Tam.

Dr. Carrie.

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

I, too, would like to get into a little bit of back and forth.

But first I want to ask, Dr. Singer—because you did have reasonable concerns about criminal penalties with these level 2 pathogens—if the bill was amended to clarify that risk group 2 pathogens would not be subject to the same degree of regulation, including security screening and penalties, whether that would help alleviate your concerns.

Dr. Peter Singer: Dr. Carrie, it would certainly help to alleviate my concerns. I would say that if there were clarity in the amendments, that level 2 versus level 3 and 4 pathogens were different, that level 2 pathogens didn't need security screening, and that the criminal penalties for level 2 were less, it would give you a better bill than what you have now.

The question I'm asking is whether that would be the best bill. What I'm really proposing to the committee is a very simple solution.

This bill is perfect for levels 3 and 4, and it needs to be urgently passed. I really support it, because there's a big gap here internationally. You don't want to have no federal power in level 3 and level 4 labs; that's not a very good situation to be in.

So the solution I would propose is to pass the bill with respect to levels 3 and 4, but with respect to level 2 pathogens, refer the question of what is the best mechanism to promote biosecurity in level 2 labs to an independent group, such as the Council of Canadian Academies. They can compare criminal sanctions, provincial laws, institutional regulations, and other types of approaches.

They may come back and say legislation is best. They would do so within two years or 18 months, and then you could amend the legislation. It would be about the same time as you'd be passing regulations for level 2 pathogens anyway, but you'd have some more confidence in the right way to go for level 2 pathogens.

That's really my position. I hope that's helpful.

● (1625)

Mr. Colin Carrie: Could I ask Dr. Butler-Jones to comment on that, so we can get a bit of back and forth going here?

Dr. David Butler-Jones: I guess my concern is the urgency of it. I think we can accommodate the concerns in terms of which bugs are in and which bugs are out, and other things in terms of the levels of intrusiveness, activity, etc. My concern is that by leaving it out, and given the amount of time it takes....

We believe we can address the serious concerns through the development of the regulatory process; otherwise, you have to come back to a new act, a new regulatory process, and that will take time.

If we have an accident in Canada in the meantime, when we have no authority and the provinces have no authority, that is a huge risk.

It was suggested to me today that one of the analogies for this is the banking system. In other words, you can regulate the big six banks, but the Bank Act actually has regulations that affect trust companies and others. It's not as if you just look at the big ones, but you actually look across all of them and have a different regime that's appropriate and scalable relative to the needs.

I was just reminded that as of February there's been an executive order in the U.S. whereby they are looking to regulate or provide oversight of biosafety in all labs in the United States. It looks as if they're moving down this path, in any case.

But whatever happens in the U.S., we need to focus on what works for Canadians and the community here. We're not going to duplicate what the Americans have done. We're going to avoid the problems that have been created and focus on a scalable approach that I think will address the issues effectively.

Mr. Colin Carrie: Dr. Matlashewski mentioned the regulations included in the bill.

I think that's a question on which we could perhaps go back a little bit with him to see what the usual process is and how you intend to bring these regulations forward, so people understand them.

Would you be okay to go back and forth on that, Doctor?

Prof. Greg Matlashewski: One of the things that concern me is that there have been some amendments suggested here. Again, it boils down to the problem of the regulations with respect to level 2 pathogens. According to this, for a first offence—a first offence—there's a $50,000 fine with respect to level 2 pathogens. That's for a first offence.

We've never had a bill like this in Canada before. We will have a bill in Canada saying that for a first offence of not dealing with level 2 pathogens, according to the regulation, it will be a $50,000 fine. It's written here in your amendments for clause 53.

I can tell you this will have an incredible impact on the Canadian scientific community. It will not put us on a level playing field; it will put us at the bottom. We will not be able to compete with other countries in terms of scientific research, and it will not provide any additional security to Canadians.

So, to me, it is a real problem just to leave the bill as is without the regulations. The regulations have to be in the bill, so these kinds of mistakes are removed and we don't have to deal with them in the future.

Mr. Colin Carrie: Could we address that over here?

Ms. Jane Allain: The first thing I would say is that with regard to the example you have from Bill C-11, in terms of how we set out the prohibitions and the controlled activities, linking back to the powers of the inspectors, as well as the licensing regime that is envisioned, the model that's used is quite a common model. We have various other examples. Whether it's the Food and Drugs Act, the Controlled Drugs and Substances Act, or the Hazardous Products Act, these types of schemes, under the criminal law power, are set out that way.

You put into regulations the specificity that you need for the different components. For example, what will the standards be for the biological safety officers? What specific conditions will you have for licence-holders? What specific elements will you need for the biosafety aspects of the bill?

The reason you frame it this way is to allow flexibility and adaptability in order to reflect in the regulations the concerns you are expressing. If you fix it in the statute itself, it's frozen. It can never be changed. It can never be amended.

The regulatory process itself is quite an onerous process. There is a duty and an obligation on the part of the government, when they go out and develop the regulations, to consult. The consulting is open, meaningful, and balanced, as they are required to do. They are required to basically prepublish what they intend to do in the regulations, in the *Gazette*, before they actually make them. There will be a period in which you will see the actual regulations and be able to comment on them. They will be reflective of the changes that are needed, or based on the intended dialogue with the various communities.

That's the first thing I would say in terms of the regulatory process and why you design a law the way you do. The second thing I would say is about penalties.

When we develop penalties for legislation, we don't do it in a vacuum. We always look at other pieces of legislation that are similar in aspects. We try to have some kind of uniformity and consistency between these different types of evidences. The rationale for this is to try for some consistency across Parliament so that when they're exercising these laws and enforcing these laws, they have a similar-type range of penalties.

I'd just like to indicate that these penalties are quite similar. Under the Food and Drugs Act, if you sell harmful food, or use misleading advertising, or prepare food in unsanitary conditions, that is a violation. A person would face three years in jail or a $250,000 fine—

● (1630)

Prof. Greg Matlashewski: I'm sorry, that's not the same thing at all. That is completely different.

The Chair: I'm sorry, we have to go on to round two. We can continue these questions.

We are going to the five-minute round now, beginning with Mr. Simms.

Mr. Scott Simms (Bonavista—Gander—Grand Falls—Windsor, Lib.): Actually, I do have a question, but I'm going to let Dr. Matlashewski respond to what was brought up.

Prof. Greg Matlashewski: If you're looking at the sale of unsafe products, you're looking at something that's completely different. What we're talking about here is a first offence regarding a level 2 pathogen.

We have to teach more than 100 undergraduate students how to work with level 2 pathogens. If they do something wrong, they are criminally liable, because it will be the first time. It says in here, "first offence". This is what's in the bill.

Ms. Jane Allain: No, but what that does is set out the maximum penalty a judge can impose if there was ever a prosecution and the prosecution ended up with a conviction. To get to that level, you have to actually go through the whole summary conviction procedure.

So it's not like a ticket is—

Prof. Greg Matlashewski: But this is the law.

Ms. Jane Allain: It is the law. And the law is setting the minimum threshold that the court would have to impose if it were going to look at it—

Prof. Greg Matlashewski: Universities will read this law and say, "We can no longer run an undergraduate teaching lab because we cannot be liable for a $50,000 fine per student if they don't follow the regulations."

Any research laboratory or any research activity in the country would be liable for doing this.

Ms. Jane Allain: It's only if they're charged with an offence, first of all. They have to be charged with an offence and prosecuted. They have to be successfully prosecuted and convicted. After that, they would face a maximum of $50,000 in fines.

Prof. Greg Matlashewski: But if this bill were passed like this, I can assure you that universities would be in an uproar over it. They would view this as a severe impediment to teaching students. This would make our country even less educated in the area of microbiology, and therefore even more susceptible to problems in bioterrorism. With this bill, we will not be able to educate people properly in this area.

The Chair: Dr. Butler-Jones, would you like to make a comment?

Dr. David Butler-Jones: Yes, just very quickly.

I think virtually every university in this country currently comes under the regulations of import-export, with similar provisions in terms of the potential to be charged. Every single university in this country is in that position. Yet in 15 years of applying it, nobody has been charged. We work with the laboratories.

So unless the universities five years ago decided to do it, I can't imagine their deciding to change their whole regime today.

Prof. Greg Matlashewski: I can tell you that when Bill C-54 first came out, every single university department was afraid and up in arms over this. These amendments have not changed that; they will not make a difference in this.

Dr. David Butler-Jones: I think it's really important as we move through the regulations.... That's clear, but people should look at their current experience working with the existing regulations and they should be reassured in that process.

The Chair: Ms. Allain, did you have a comment you wanted to make? Your light is on.

Ms. Jane Allain: No, sorry.

The Chair: Mr. Simms.

Mr. Scott Simms: I don't know if I have much time, but let's find out.

The Chair: You have a minute.

Mr. Scott Simms: Okay.

Would you agree or concur with what Dr. Singer said about the fact that the level 2 aspect of it should be brought forward to certain groups, like the academic groups, before you enact it, so that it would be carved off into something different and consulted on before you get into the situation that you're talking about because of the concern raised by the community?

Prof. Greg Matlashewski: I agree 100% with what Peter Singer has been saying.

Mr. Scott Simms: I still have time, right?

The Chair: You have 30 seconds.

Mr. Scott Simms: Pardon my newness. I understand the impact of the risk group 3 and 4 situation—I get that—but why should the government bother with these agents that pose no public health risk, such as, for instance, a lab worker in contact with a micro-organism and he or she gets sick and it doesn't go beyond that? I don't really understand what it is you're looking for in this.

The Chair: Who would like to answer?

Mr. Simms.

Mr. Scott Simms: You're explaining it to someone who knows very little.

● (1635)

The Chair: Ms. Tam.

Ms. Theresa Tam: The risk group of pathogens, like salmonella, or the E. coli that caused the Walkerton incident, when grown in certain concentrations are dangerous. It is important for laboratory workers to be protected against those pathogens and apply the laboratory biosafety guidelines.

A number of these pathogens can be spread, if it's an enteric pathogen, to the immediate family or to their community. If someone chooses to access them for nefarious means, for bioterrorism events, then they're obviously more prevalent. We're not concerned about the biosecurity piece as much for risk group 2, but we are concerned that they are still pathogens that cause disease in humans and must be handled according to good biosafety practices.

If we left it to, of course, provinces or research councils or private labs to do things differently, what you would end up with—and actually it's the gap today—is an extreme patchwork of some people following these, like these good researchers, and then there are laboratories that do not follow laboratory biosafety procedures. Level 2 pathogens can cause significant disease in humans.

The Chair: Thank you.

Mr. Uppal.

Mr. Tim Uppal (Edmonton—Sherwood Park, CPC): Thank you, Madam Chair.

Thank you all for coming back again.

There's something from the previous testimony that I was thinking about. There are approximately, we were told, 4,000 labs with human pathogens and toxins that are not subject to any form of regulation in Canada in operation right now. How confident is your department, and you as a security expert, that these labs are following proper biosafety practices right now?

Ms. Theresa Tam: After the bill is passed, upon royal assent, we actually will be able to get in touch with these labs.

At this point in time, it's not easy to say what labs are using proper biosafety practices, but we've just had some very recent experiences of laboratories that fall under the radar of any research or academic institutions that are working with level 2 pathogens and have very worrisome practices, including abandonment of pathogens with no indication as to what's in their inventory. This has occurred on more than one occasion.

So we do know that there are labs in this country that are handling and storing significant pathogens, but we don't know where they're located or who are the people in them.

Mr. Tim Uppal: Thank you.

Dr. Singer.

Dr. Peter Singer: It's a really good question. I'd be interested in the comments from David and company.

I would say that you could have a pretty good assurance that most of those labs are well regulated, because most of the 4,000 are probably in universities and in private companies that are a little bit more complicated. For instance, at the University of Toronto alone, there are a few hundred level 2 labs, and when you start adding up universities, you're getting towards that 4,000 number.

I think one can have reasonably good confidence that universities have biosafety procedures, good accountability frameworks, by and large, and granting agencies coming in and out, etc. I also suspect that what Theresa is saying is also true. At the margin, there are probably some laboratories that may not.

The question really is one of burden and benefit. To get those laboratories, which is the benefit I was asking about in my initial comments, against the negatives of the criminal law and the fact that, as I said in my earlier remarks, there might even be a false sense of security, because by regulating pathogens you don't regulate everything, I'd just be more comfortable on the level 2 stuff.

I appreciate everything they said. It's somewhat convincing. I'd just be more comfortable on the level 2 stuff and would really think a little bit more carefully about what the best way to create biosecurity would be. I proposed a mechanism to do that.

Mr. Tim Uppal: We've heard from the department on a couple of different notes: on the criminal penalty side of it and on the way they would regulate level 2. Does that not make you feel better about the level 2 stuff, or are you still convinced that it needs to be completely out?

● (1640)

Prof. Greg Matlashewski: I'm still concerned if the bill says that for a first offence there's a fine of $50,000. I recognize that it used to be $250,000, so now I will be fined $50,000 instead of $250,000. I can see that they have moved on that.

But I would like it to be zero, because on level 2, with the 4,000 labs and thousands of graduate students and thousands of professors working on level 2 pathogens in this country, I don't think they should be faced with a new bill that criminalizes you if you make a mistake in working with level 2. So if you mislabel something, if you put something in the wrong location, or even if you send something without proper—

Mr. Tim Uppal: But do you honestly feel that would take you to a $50,000 fine? What our legal expert is saying is that it would have to go through some kind of court system or there would have to be charges laid.

Prof. Greg Matlashewski: But it's very simple to do it if it's in the law. The law would be written.

Ms. Jane Allain: The law doesn't allow the government to basically issue a fine. What that does in there is set out the penalty. It does not allow them to issue the fine for $50,000. They still have to go through a court process. There still has to be a charge.

Prof. Greg Matlashewski: Sure, but it's a criminal charge.

Ms. Jane Allain: It's a summary conviction charge. It's not an indictable offence. That, from a criminal law perspective, is a much lesser procedure.

Prof. Greg Matlashewski: And every student in our undergraduate...? We have 350 undergraduate students in microbiology and immunology. We need to train those students. Otherwise, this country will not be able to deal with bioterrorism and pathogens—

The Chair: Dr. Butler-Jones, would you like to...?

I would ask everybody to please pay some attention to the chair. I'm trying to be as lax as I can. Let's try to do this, okay? I taught junior high. I can handle this.

Dr. Butler-Jones.

Dr. David Butler-Jones: As Jane is saying, it's not a fines system. It would require a charge, etc. I can't imagine anybody in their right mind charging somebody in that position.

Certainly, all the universities are currently in that situation in terms of the importation and export of pathogens. We haven't charged them. We work with them. The committee has heard from university biosafety officers and others who say this will help to level the playing field with those who are outside. We're most concerned about the exceptions. We will, through consultation and discussion, make sure that in fact the burden is a minimum, if anything. We've been reassured by biosafety officers and others that there really is no additional burden if you're already doing basic, good biosafety.

The other thing is the issue of fines. Having worked with fines and issues for a long time, I know that in public health legislation there are often very large fines and jail terms. That is the very, very last resort with the most egregious situation, and you still have to take them to court. You don't take people to court unless there is an egregious and impossible situation where nothing else has worked.

As for the notion of the scenario that you're suggesting, it's virtually impossible in my mind and in my experience to go down that route. It serves nobody well.

You're right, in that if we did take that approach, yes, it would do that, but who would ever do that?

The Chair: Ms. McLeod.

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

Just as a quick reminder for me, how many level 3 and 4 labs are there in the country?

Ms. Theresa Tam: There are only two laboratories at level 4, and they belong to the federal government and are situated in Winnipeg. There are approximately 130 level 3 laboratories. We believe the majority of those—almost all—are already importing pathogens. They essentially already have permits under the human pathogen importation regulations, so we know they're following laboratory safety procedures.

Again, with that in mind, we do not believe the regulatory and programmatic elements will have massive impacts on these laboratories, which are already following laboratory biosafety guidelines.

For select level 3 and 4 laboratories, we are going to be looking at security clearance applications. So that would certainly be one of the key elements that will impact them.

Mrs. Cathy McLeod: Dr. Descoteaux did quite a scenario around the research they are currently doing on AIDS and sample banks, so I'm just wondering if I could hear really clearly articulated how this bill might impact this important work, because I believe you were saying AIDS is 2.9. What will happen in terms of that particular example?

● (1645)

Ms. Theresa Tam: For all laboratories, what's currently envisaged is a phased approach. The initial phase upon royal assent is very simple. The impact on them is that they have to call us and make sure we know who they are and that they're only holding level 2 pathogens, or whether they're holding certain level 3 and 4 pathogens. They shouldn't have smallpox under this type of requirement. We certainly have bounced these kinds of impacts off our risk group 2 labs, and they don't believe there will be major impacts during this initial phase.

For risk group 3s, we are prepared to have discussions with the community, because we do not believe that all risk group 3s are created equal; hence, to only a certain number of them would the biosecurity elements apply. So if you are an HIV researcher, we do not believe that HIV is likely to be used as a bioterrorism weapon, so it will not be treated the same as something like anthrax.

So that will come under the regulatory design of the program at that point in time. That discussion still has to take place, but essentially the risk-based approach will take that into account.

They will obviously be looking at inventories, for example, and certainly making sure that with risk group 2s we don't have risk group 3s inadvertently mixed up with them, or those types of things. But we're not going to ask for detailed inventories for those labs.

As for risk groups 3 and 4, the 3s will be under further discussion —again, depending on which risk group 3 pathogens you have. For HIV, if it's feasible and effective just to say, well, we have handled HIV, that could be it, but we need to know which laboratories are handling HIV.

Again, what we want to do is to design something that has as little impact as possible. But if you are already filling out the forms for the human pathogen importation regulations, when our regulations come into force—which will probably be in many years' time—we will be looking at effective ways of incorporating them into one administrative procedure. So the scope of the licence will include the importation elements in it and you will not be trying to do two things; we'll be trying to deal with both the domestic and the importation piece together.

The Chair: You just have one more minute, Ms. McLeod.

Mrs. Cathy McLeod: Certainly, from my perspective, the development of regulations is quite a technical piece. Certainly, even with my medical background, which is much less than that of many of our guests here, I believe in setting a framework. I'm actually surprised it was suggested that we put a lot of the regulations right into the legislation, because I would have thought the scientific community would prefer a different process.

I just wanted to make that point in my last minute. Thank you.

The Chair: Thank you very much.

We'll now go to Monsieur Dufour.

[*Translation*]

Mr. Nicolas Dufour: Thank you.

From the outset, Dr. Butler-Jones told us that you had looked at legislation in other countries to get an idea of what aspects could be included in Bill C-11. However, the scientists have shown us that the list is much shorter in the United States and that we should perhaps move in that direction rather than the much more rigid structure of Bill C-11.

Just now, the scientists told us that, because of the proposed fines, they feel that they are under attack, even before the bill is passed. They are already being treated like criminals. As you know, people have to be found guilty before they can be fined. We must not forget that legislation exists to be used.

I am surprised by one thing. Fines can be imposed, but on whom? Is it the universities, the hospitals, the professors? We all know that this is provincial jurisdiction.

On the one hand, you tell me that the legislation will not be challenged, that it will move forward and that the provinces see no problem with it. On the other hand, who gets fined? If we start fining hospitals and universities, we are going right into provincial jurisdiction, it seems to me.

● (1650)

[*English*]

The Chair: Ms. Allain, do you want to address that?

[*Translation*]

Ms. Jane Allain: First, as I mentioned previously, this bill does not give the Public Health Agency of Canada the power to impose fines. It is wrong to believe that the fact that a fine is set at $50,000 gives us the power to impose it. On the contrary, it establishes a penalty, and, to determine the penalty, you first have to look at the activities that are regulated and what the people have to commit to as a result. So, essentially, a licence holder must, for example, contravene one of the conditions of his licence or fail to comply with the law. After an inspection, or some other investigation, the person could be prosecuted. In other words, a summary charge could be laid. With a summary charge, penalties and procedures are much less onerous. Essentially, that is the mechanism that Parliament provides for establishing criminal penalties.

So it does not mean that we can impose fines on anyone. It essentially provides the ability to prosecute people who contravene the law. As Dr. Butler-Jones said, it would be just in cases where people did not comply with instructions given by inspectors, and it would depend.

I would also like to emphasize that the bill as written provides for the due diligence defence. So if a person has taken legitimate and reasonable precautions established as his obligation and duty under the regulations or the legislation, it is a full defence to section 53. It would then be a question of the penalties intended for risk group 2.

This is a procedure that allows the government to bring prosecutions, but only if the act is contravened. Ultimately, it is up to the court to decide if the act has been contravened and if the accused should be found guilty. I should mention that the penalty indicated is the maximum. It is very rare for a court to impose the maximum penalty in anything but an extreme case. Penalties are determined completely within the scope of sentencing principles that a court must consider. For example, the person's behaviour is a factor. A court would impose a maximum penalty only in cases where there had been prior warning, where the accused had not followed the guidelines, or where he had flatly refused to observe the law.

[*English*]

The Chair: Dr. Butler-Jones, would you like to comment?

[*Translation*]

Dr. David Butler-Jones: We do not regulate laboratories or hospitals. This legislation deals with pathogens and is applied only in that context.

In the United Kingdom, the legislation on pathogens contains more than 15 pages and puts levels 2, 3 and 4 together. That is one example.

Mr. Nicolas Dufour: Did you do a ...

[*English*]

The Chair: I'd ask you to defer. It's now Dr. Bennett's turn.

You have my apologies. You had a little bit more time.

Hon. Carolyn Bennett: I would like to give my time to the witnesses who have been called so that they can ask the officials whatever questions they want in terms of whether they're satisfied. Mainly it is to ask the witnesses whether it would it make them feel better if the regulations came back to this committee and if the process for coming to the regulations were to be better articulated in the bill, in terms of “thou shalt consult”.

Who would like to have my time?

The Chair: Go ahead, Monsieur Ouellette.

Prof. Marc Ouellette: Thank you very much.

When Bill C-54 first came, and then Bill C-11 afterwards, it was like an atomic bomb in the research community. We were not prepared for it. The way we read the law—and I even read the document explaining the law—it was appalling to the people in the community who had been following the guidelines for those 15 years.

At level 4, there's one big lab in Winnipeg. At level 3, there are 120 labs, but most of those level 3 labs are not dealing with biothreats. Yes, there is HIV, and a couple of them deal with TB. The labs that have to work with anthrax are mostly military labs. I know *Burkholderia pseudomallei* is being worked with in Calgary, and possibly they have special arrangements there.

When I came the first time....

● (1655)

[*Translation*]

The regulations governing the import of pathogens are already very, very substantial. We do not know what the process of communication will be between the people on the ground and those who will be making the regulations. It is certain that level 2 will be different from levels 3 and 4, but that is not how the bill is written.

[*English*]

I understood very well when you said, “Well, gee, if I was in your place I would not like to have regulations within the law”. This is not our field of expertise, and for us, when we read that, it looks pretty dangerous for the research we are doing, in the sense that we will overburden already overburdened people. Now with the regulations, I'm not aware of how the process will work, or whether it will come back to this chamber, or whether there will be communication. It's a *chèque en blanc* that they're asking for. You want something more from the Public Health Agency of Canada than a *chèque en blanc*.

Dr. David Butler-Jones: There are two things.

One is that we will be consulting on the consultation process for the development of regulations with provinces and territories, stakeholders and others to make sure we have the consultation process right and we have all the issues right in terms of what people have raised. That will be transparent, that will be open, and there will be many opportunities, bilateral, multilateral, a whole range of things, and people will see it. It's up to this committee, and ultimately the House, what will come back where, and we're quite comfortable with however you wish to handle it.

There is an irony to it all. This is now several iterations of trying to get a bill on this to pass. The previous one was much more specific, and what we heard in all the consultations from across the country, from our colleagues in research and others, was to make it less specific, because they don't want all level 3 pathogens in. They want some time to think about what should be in and what should be out, and with level 2 and how to manage that. Make it less specific and then deal with it in the regulations, which are more amendable if there are new pathogens or new issues, etc. We changed it in that way, but now the concern is that it's too general and too complex. It was done based on our colleagues in science and elsewhere saying not to make it so specific, but make sure they're consulted well on what's in, what's out, the regulatory regimes, and all of that kind of stuff, which is our intent and our plan. That's how we will proceed, depending, again obviously, on how the House pursues this legislation.

The Chair: Thank you.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: I'm a little leery about the suggestion that the proposed reduced penalties for people handling level 2s will never be used except in extreme cases, and of course it has to go through the courts and a judgment has to be made, blah, blah, blah.

It seems to me that just the threat of it being there is the problem, that this has the impact on the scientific and research community. Even if one argues it will never be used, it is, as was just said, like giving a blank cheque.

Again, the more we talk about this, the more I'm wondering about why we would even go this route. Maybe we should actually look at getting rid of level 2s for now, as Mr. Singer said, and get on with 3s and 4s. Leave it the way it is; have your regulations that deal with 3 and 4. They'll come to this committee and we'll have some oversight, but keep in mind that we don't get a chance to change the regulations. It is a blank cheque. We can review them with the amendment I proposed, we can comment on them, we can consult on them, but if the government insists, we can't change them. It's only a little bit of a check and balance in place.

Given all of that, can we revisit this once more, everybody together, and say, what's wrong with just deleting level 2s for now?

In fact, I originally had an amendment to do just that, to change clause 7, amend it after line 22 on page 5, saying that the subsection does not apply to any activity involving a micro-organism, nucleic acid or protein that is listed in schedule 2. What's wrong with that?

● (1700)

The Chair: Dr. Butler-Jones, would you like to answer that?

Dr. David Butler-Jones: The first thing is that in terms of the issue of potential penalties and prosecution, 3,500 current labs are currently under a regime that has that option. It has not changed their practice. In the U.K., it did not change or stifle or put a chill on research.

It's a hypothetical about whether this will make.... I think it will make some people feel more comfortable if it's removed. It will make me somewhat more nervous. Given the things that we're aware of in terms of things being abandoned and left behind, the mix-ups, people saying they're only level 2 but working with level 3, quite honestly we don't know what's out there. It's not like we want to create a great imposition, etc.

But I am worried about, the outliers, as Peter mentioned. If there's a mistake, if there's a problem, if there's a release, if there's a lab playing with anthrax and it gets released—not intentionally but because they don't have good biosafety—that is a concern.

There was an anthrax outbreak in the U.K. There was the H2N2 incident. That is my concern. Ultimately, it's up to legislators. I've said my piece. That is my concern—if there is a mistake.

We think we can accommodate the concerns through the regulations, but if in the meantime something happens, I would be concerned about that and it would be difficult to justify.

The Chair: I think Mr. Descoteaux wanted to make a comment. All of these comments are on the record and it makes us very responsible. Take your time.

Dr. Albert Descoteaux: The problem I have is that you always use fear. When you were talking about level 2 pathogens and anthrax releases, accidents, you were saying you're nervous about accidents happening. Even with this law in place, it will not prevent any accident, any spill, any release. I'm sorry, but prove to me that Bill C-11 would protect us from an accident, from a release, from a spill in the environment.

You're always talking about somebody who could work with smallpox or somebody who had anthrax....

Dr. David Butler-Jones: I did not say that.

Dr. Albert Descoteaux: That's what Mrs. Tam said earlier. We're talking about level 2 pathogens.

The Chair: I think Dr. Butler-Jones was trying to say something. Go ahead.

Dr. Albert Descoteaux: I want to know how this bill will protect us from an accident.

Dr. David Butler-Jones: Sorry, I don't mean to interrupt, but I did want to say that you're right, accidents will happen. There will be surprises. The advantage is in actually knowing who has what and that there are some basic standards in terms of biosafety.

Again, as I've said, I'm not worried about the university labs, and I'm not worried about places that have these things in place, but there are the outliers, and currently there are no authorities to deal with them. There is a limited ability to compel a lab that is an outlier. There is a limited ability to say, “What do you have and where have you sent it?” There is a limited ability to track it down, as we were able to do with the H2N2. We were able to very rapidly track it down and tell the labs they had it so that they could destroy it.

In the absence of the ability to do this, then we could not do that, and I'm not sure what would happen. Again, it's a relative risk issue and an issue of the level of tolerance of risk. At this point in the environment, I'm giving you my opinion from a public health perspective because we think we can minimize the impact of this. We think we can do it in a way that will not put a chill on or create problems for researchers and that will minimize the paperwork.

But at the same time, it will give us some assurance that, should there be a problem, we have some authority to do something that provinces currently do not have. There's a very varied regulatory regime across the country and this would be complementary to provincial activities. It would not duplicate or interfere with what they're doing.

● (1705)

The Chair: Ms. Davidson.

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

Again, thanks very much to our presenters.

There's some interesting discussion here again today.

Dr. Butler-Jones, I think you may have just answered the first question that I was going to ask. We've talked about the two level 4 labs and we've talked about the 120 level 3 labs. We've also talked a lot about those where we don't know what they have. Are they included in that 120 or are they over and above that?

Dr. David Butler-Jones: We think it's unlikely that there are level 3 labs that we're not aware of because of imports and exports and academic labs, etc.

You don't know what you don't know. We're estimating that there are 4,000 labs that do not come under import-export. Some of them, as have been identified, are university labs and come under their regime, but we don't know what we don't know.

Mrs. Patricia Davidson: Okay. So are those the ones you just indicated in your last comments that you're concerned about because there's no regulation? You can't—

Dr. David Butler-Jones: It's the ones that we don't know about that I'm worried about. I'm not worried about the ones that are based in universities and have their own regimes already in place.

Mrs. Patricia Davidson: Yes. This legislation would help correct that.

Dr. David Butler-Jones: Correct.

Mrs. Patricia Davidson: If we don't pass this legislation, there's nothing, where we are today, that will protect the public from the ones that are not reporting now.

Dr. David Butler-Jones: As members and others have identified, I think there are levels. If we remove level 2, it will give us this at least for level 3 and level 4, but by and large, if we know about them, they're already under the regulatory regime.

My concern for the potential risk to public health is in the level 2 labs that we don't know about and that aren't under some kind of regulatory regime. If we don't include them, that will leave a big gap, in my view.

Mrs. Patricia Davidson: Okay.

Could you or one of your colleagues also please go over the regulatory process again? As opposed to the legislative process of passing the bill and then doing the regulations afterwards, which is normally the way that government bills are done, is there a reason why it can't be the other way? Does it make the regulations more difficult to change, as I think I have heard? Or does it make them impossible to change? What's the problem with doing that?

Dr. David Butler-Jones: Certainly, acts are more difficult to change than regulations. They all require processes. We cannot actually start on the development of and consultation on regulations until we actually have an act of Parliament that gives us authority to do that.

Mrs. Patricia Davidson: So you need to have the act to begin with.

Dr. David Butler-Jones: In the way it's normally structured, yes, but as has been described, you can ask for the regulations to come back, or you have any number of options.

Mrs. Patricia Davidson: Yes.

Do you have something else to add, Jane?

Ms. Jane Allain: The only thing I would add is that the regulations have to comply with what Parliament has given the Governor in Council the authority to do. The Governor in Council can't do anything beyond the scope of what you've set out as their limits in the statute itself. The only kind of regulations they can bring are the ones that are enumerated in the statute itself. They couldn't create new offences, for example. They couldn't create a new category of schedules. That would have to be determined by Parliament, not by the Governor in Council.

I would describe the process for developing regulations as being much more flexible. It's a much more inclusive and transparent process in the sense that the government must go out and consult. The directive on how you consult is very clear. The consultations have to be open, they have to be meaningful, and they have to be balanced. As well, they have to actually include that in a document when they do their analysis. It's called a regulatory impact assessment, and they basically have to describe how they've done it before they actually make the regulations. They have to prepublish the regulations. There has to be a period during which these regulations are in the *Gazette*. They're open to comments by the public as well as the stakeholders they've engaged with. They take these back and then finalize the regulations before they actually table them and gazette them.

So it's quite a process. It does take a long time. This will take about two years.

● (1710)

Mrs. Patricia Davidson: Is it possible to exempt level 2s from any type of criminal charge? That seems to be a big concern.

Ms. Jane Allain: No, there wouldn't be that ability to exempt them. You've created the architecture under the criminal law power that sets out the range of penalties you have. We could not exempt them from the criminal law.

The Chair: Yes, go ahead.

Prof. Greg Matlashewski: I'll be very brief.

We're not saying that level 2 pathogens shouldn't be regulated, or that there shouldn't be a list of every lab working with level 2 pathogens. We're not saying that. What we're saying is that level 2 pathogens should not be under the same bill as level 3 and level 4 pathogens. They don't belong there.

So level 2 pathogens should be dealt with, but not under the same bill as level 3 and level 4 pathogens. They are very different organisms. It would be a mistake to have them within the same bill. They still have to be dealt with, but in another forum.

The Chair: Dr. Butler-Jones, I think you wanted to make a comment.

Dr. David Butler-Jones: Yes, just very briefly.

There are two mechanisms to do that. You can have two bills and two different sets of regulations, or you can have one bill and different regulatory regimes to address it, which is what we've proposed. It would address, actually, the concerns. There would be a clear difference in terms of how they're handled.

The Chair: Dr. Carrie.

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

I wanted some clarification, Dr. Butler-Jones, on the university laboratories in Canada. Do most already import, to your knowledge?

Dr. David Butler-Jones: It will vary. I think many university labs do not. Again, it depends on the kind of work they're doing. But if they do, then they're already there.

My anticipation, from talking with biosafety officers and others in academics, is that they have their own biosafety officers for universities. They have laboratory standards and so on. They say that, for universities in particular, this should not be a burden, whether they're importing or not.

All we're asking people to do is to follow the national biosafety guidelines, basically. That's what biosafety officers expect of their academic labs.

Mr. Colin Carrie: Okay.

I also wanted some clarification from Dr. Tam. This is something that Dr. Singer might want to comment on as well.

When we're talking about level 2s, Dr. Singer's word is “biosecurity”. When you are talking about this actual bill, Dr. Tam, you're talking more about “biosafety”. I'm wondering if you could give me a little bit on the difference between the two, and the intent of this bill with level 2s.

Ms. Theresa Tam: Yes, as I said, we're mainly promoting a uniform standard across the country in terms of good biosafety practices. We still believe that is absolutely important for level 2 pathogens. We do not believe that they are of the biosecurity risk—i. e. the use of them for bioterrorism acts or security breaches—as select level 3 and level 4 pathogens.

It has always been the intent of the program that we treat risk group 2 less stringently but still recognize that they're dangerous organisms. I think Canadians feel we should know who possesses dangerous bacteria and viruses. We should know who has them, we should know that they are contained in the right environment, that there are good biosafety practices around them, and how they're transferred domestically.

Our European colleagues, who had an incident where a research lab disseminated, inadvertently, a rather nasty influenza virus, the H5N1, along with one of the H3N2 viruses, asked us whether, if this happened domestically and things were transferred from one province into another province, we would have any authority or be able to handle that situation. Right now we're not able to do that. Knowing who has what and who is transferring which organisms will allow us to rapidly handle a situation like that as well.

Mr. Colin Carrie: Okay. There still seem to be concerns about the timelines considered for the development of regulations. What timeline are we looking at to develop the regulations?

Ms. Theresa Tam: Given the process that Jane has outlined, we wanted to initially farm out our consultation strategy for people to provide comments on it. We believe it would take about two years. We don't take the making of regulations lightly; we want something that would actually work in Canada. I think that would be about two years. In terms of then trying to implement the program and look at the feasibility of implementation, we believe we're about five years out from when the regulations will come into force. And then we'll proceed to the third phase of implementation. The initial phase, as I said, upon royal assent, is relatively light in terms of requirements.

● (1715)

Mr. Colin Carrie: In your view, that gives us a good amount of time to explain and consult with the different stakeholders.

Ms. Theresa Tam: Yes, it will be two years of consultations.

Mr. Colin Carrie: Did you have discussions with the Privacy Commissioner? What were the results of those?

Ms. Theresa Tam: Yes, I did. I think the Privacy Commissioner was obviously also asked to comment on this bill under short notice. So we did explain to the Privacy Commissioner that we are interested in the pathogens and how they're handled and contained. We're not interested in personal information to do with the patients that the samples have come from, for instance.

They were also interested in, say, if the SARS virus escaped from a lab, infected a lab worker, and then infected the family members, whether we would then know personal information about family members, etc. I think from our perspective we're interested only in what happened in the lab that resulted in an infection and how we could actually do that better, as opposed to the public health domain, which will take care of the patients who are ill and the family members. So there is no need for us to have that kind of personal information.

They were also interested in our security clearance and what we are proposing. We are not proposing anything different from security clearance practices and how we hold information along the lines of other government departments that demand security clearance for other purposes.

They were satisfied with that explanation, and we reiterated that we will be doing privacy impact assessment on the program during the regulation development and as we are moving into that with them, and they were very satisfied with that.

Mr. Colin Carrie: That's good.

Dr. Singer—

The Chair: I'm sorry, Dr. Carrie, time is up now.

I would like to thank the witnesses.

I do think that we, as a committee, need five minutes or so to have this discussion within our committee. We have some things to consider about the bill, and we need to have some dialogue.

You have been so wonderful and so patient in coming back and answering our questions over and over again. I can't thank you enough.

Dr. Singer, I understand that you just ran off the plane and got here barely on time.

Dr. David Butler-Jones and your team, Dr. Tam and Ms. Allain, I know that you have been back numerous times as well, as have the other three. We appreciate all your input and take it very seriously.

If you wouldn't mind, I would like to go in camera for a little while to have a discussion with my committee on how we should proceed from here on in. Would everybody who is not supposed to be in the in camera session mind leaving the room? I would really appreciate it, because we just have a few short minutes left.

We'll suspend for one minute.

Thank you.

[*Proceedings continue in camera*]

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