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Chair

Mrs. Joy Smith

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● (1530)

[*English*]

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

I certainly want to welcome our witnesses today. We're quite looking forward to what you have to present to us on Bill C-11.

Committee, as you know, from each organization there's one person per organization who's going to give a 10-minute introduction.

We have in front of us, from the Association of Medical Microbiology and Infectious Disease Canada, Alicia Sarabia, who is section head of medical microbiology at the Credit Valley Hospital. Welcome, Doctor.

We have, from the Ontario Agency for Health Protection and Promotion, Vivek Goel, president and chief executive officer; and we have Don Low, medical director of public health laboratories. Welcome to both of you here today.

From the University of Calgary, we have Dr. Michael Hynes, professor, Department of Biological Sciences. Welcome, Doctor.

And from the Institut Armand-Frappier, we have Dr. Albert Descoteaux.

We welcome you all.

We will start with Dr. Alicia Sarabia.

Dr. Alicia Sarabia (Section Head, Medical Microbiology, The Credit Valley Hospital, Association of Medical Microbiology and Infectious Disease Canada): Thank you for inviting me to speak today.

First I would like to give you a little bit of background information. I'm an infectious diseases specialist and medical microbiologist working out of the community lab situated in a hospital, the Credit Valley Hospital in Mississauga. I also have a fair amount of experience working with community or what are otherwise called private labs in the province of Ontario. I have less experience working in academic-based laboratories, but I've sought out the opinions of my colleagues in those areas in order to represent them well today.

I'm chair of the microbiology committee of the Ontario Medical Association's quality management program. This program tests proficiency amongst all licensed diagnostic microbiology labs in the province. So I have a feel for the lab work that's going on in our province with regard to diagnosis.

As you know, I'm also section head of medical microbiology in the national Association of Medical Microbiology and Infectious Disease.

Now for a little bit of background and a very high-level description of diagnostic labs in our country. The labs are based out of a number of different settings. They are based out of hospitals and community labs, most of which are privately run. And they are based out of the public health laboratories, which often serve as referral labs for work that takes place initially in the hospitals and private labs and then is brought into the public health labs for investigations of such things as outbreaks, for example.

There is a huge variation among these labs. Some labs are very, very small. They are run by a handful, literally, of people who may be trained not only in microbiology but also in chemistry and hematology, for example. Then other labs are run by hundreds of people, and they're very sophisticated, complex organizations.

The volumes of specimens will vary tremendously across the laboratories, as will the diagnostic platforms. Some labs will do some very basic microbiology, such as basic testing on throat swabs submitted to them, while others will do all sorts of testing, such as diagnostics to look for viruses, bacteria, parasites, and fungi.

This all needs to be taken into account when we study the legislation, especially considering the potential work, resources, and administrative changes that will be required of some of these labs.

The research labs can of course be based out of academic centres and public health labs as well as many private laboratories across the country. Canada has a strong reputation in research within the realm of microbiology. We see, in medical journals and international meetings, representation by our Canadian research labs in microbiology.

Bill C-11, as we all know, focuses on biosafety and biosecurity. I understand the footprint associated with biosecurity has become a bit smaller as the legislation has become more refined. It does take off from current lab biosafety guidelines published in 2004. My understanding is that the playing field is to be levelled for all labs across the country so that regulations can ensure that labs practice the same way when it comes to biosafety and biosecurity, depending on the risk associated with the pathogens being processed in their midst.

Our recommendations and concerns are as follows. I'd make a comment first, that we do applaud, of course, the focus on biosafety and biosecurity because it does reflect the culture of concern for public health. We worry, perhaps, that public health may be compromised if the program and regulatory frameworks associated with this bill are too restrictive, thereby limiting lab efforts and diagnostics and research.

So we feel that it is very important to strike a balance in the interest of preserving and improving public health, and thus have lab biosafety/biosecurity on the one hand, but also continue to produce essential research and diagnostic findings on the other hand to maintain the public health of our citizens.

● (1535)

When it comes to the functional application of the legislation and the regulatory framework, we're not quite sure what's in store for us. There have been information sessions that have been held by the Public Health Agency of Canada, and some questions have been addressed. But because the legislation is still fairly high-level, we're still not clear—some of us—as to what the details will entail. It does leave some of us asking if that balance of biosafety and biosecurity against advancing diagnostic research findings will remain.

We strongly feel that a good solid communications structure will need to be built in order to have this work out. A respectful, open, and bidirectional flow of information between the Office of Laboratory Security at the Public Health Agency of Canada and the key stakeholders—including AMMI Canada, my organization—will be required for this to be successfully implemented and executed.

During the development of this framework, issues like the following will require review in much greater detail.

We need to know exactly, or work together to determine, what the implementation timelines will be. We would recommend that a phasing-in of the various elements of the program occur, rather than that everything happen at once.

We need to know and discuss details of the security clearance criteria. These, of course, need to be clearly defined. And we need to discuss the impact of authorization, of keeping tabs on individuals entering and exiting labs, on the workload of laboratories versus their resources for managing it. How can this happen?

We need to know more about the nature of inventories that will be required by labs possessing various risk group pathogens. We strongly feel that tools, for example, need to be developed by the Office of Laboratory Security in conjunction with stakeholders so that people aren't inventing their own wheels to comply with the regulations.

We also feel that the Office of Laboratory Security and its key stakeholders need to discuss opportunities for maximizing efficiencies. In Ontario, for example, we're inspected by a provincial group that ensures biosafety and security. In order to import pathogens from the U.S., for example, we already fill out a questionnaire that's about 21 pages long, and it takes weeks to months, sometimes, to fill it out. So we have to ensure that in being compliant with this important legislation we're not up to the ceiling with paperwork.

Also, I think we need to further fine-tune the security requirements, depending on specific organism biosecurity risk. In the legislation we refer to risk group pathogens. I feel that even within one risk group—let's say risk group 3—there are pathogens that present varying levels of biosecurity risk. We need to refine this more so that the resulting program becomes a practical, feasible, and safe piece of legislation to work with.

In closing, I'd like to say that, again, the objective is to achieve a balance of biosafety and biosecurity within our labs while maintaining excellence in diagnostic and research efforts to promote public health. To have this occur, we need that very strong communication structure. And we need to know that the resulting regulatory framework and program are really a function of the partnership that will exist between the Office of Laboratory Security and its key stakeholders.

Thank you.

● (1540)

The Chair: Thank you so much for your insightful comments.

We'll hear from Dr. Goel, president and chief executive officer of the Ontario Agency for Health Protection and Promotion. You're next up.

Dr. Vivek Goel (President and Chief Executive Officer, Ontario Agency for Health Protection and Promotion): Thank you. Good afternoon. I would like to thank the honourable members of this committee for the invitation to present to you today.

Biosecurity is clearly a significant issue for Canada, and I'm pleased to share comments and recommendations on behalf of Ontario's new public health agency.

My name is Vivek Goel. I'm a public health physician and the agency's president. I'm also a professor at the Dalla Lana School of Public Health at the University of Toronto. Joining me today is Dr. Don Low, the medical director of our public health laboratories, microbiologist-in-chief at Mount Sinai Hospital, and professor of laboratory medicine and pathobiology at the University of Toronto. Dr. Low is one of the heroes of SARS, who worked tirelessly throughout the outbreak to help protect the health of Canadians. Since then he has been outspoken in his commitment to the renewal of our public health laboratories.

The Ontario Agency for Health Protection and Promotion was created by legislation in 2007 as a result of a number of expert panels and task forces established post-SARS. Similar to the creation of the Public Health Agency of Canada, the goal is to strengthen the public health system. Among other things we provide specialized scientific and technical advice and on-the-ground support to front-line health care workers, public health units, and government. We have a broad mandate that includes infectious disease control, health promotion, chronic disease and injury prevention, environmental and occupational health, and health emergency preparedness, including assisting in responses to bioterrorism.

On December 15, 2008, the Ontario public health laboratories transferred from the Ministry of Health and Long-Term Care to the OAHPP. More than 600 staff work in the public health laboratories, which operate in 12 sites across Ontario. Our labs perform over four million laboratory tests annually. Our ability to generate laboratory data and use it efficiently and effectively to generate tools and technology to inform the public health and broader health systems will be key to our success.

The proposed legislation is laudable in its attempt to codify into statute a number of existing biosafety and biosecurity guidelines, and it addresses an issue of critical importance. We appreciate the information sessions that have taken place and the revisions that have been made. We also appreciate recent assurances we received from Dr. Tam and Dr. Butler-Jones that there will be further consultation, particularly as regulations are developed. We look forward to having an opportunity to truly provide input.

We have concerns related to several specific areas of the proposed legislation, particularly given the absence of draft regulations. We would prefer to see the most critical issues addressed in advance of passage of the legislation.

As drafted, the legislation confers broad powers on the minister in the use of a long list of pathogens and toxins. Based on the legislation alone, the potential for duplicate regulatory licensing and inspection regimes is very significant. The potential workload implications and resulting delays could significantly impact on the operation of clinical, public health, and research laboratories.

The bill provides for broad regulation-making powers. These powers relate to a broad range of topics such as facilities, security clearances, inventories, and licensing. In addition, the proposed legislation includes a provision whereby regulations may incorporate by reference any documents produced by persons or bodies other than the minister.

Given these broad powers, including the incorporation by reference, and the broad range of topics that may intrude into areas of provincial responsibility, it would be preferable if the bill included an explicit obligation on the minister to undertake public consultations. We recommend that the bill be amended to include a specific notice requirement, such as a publication advance of 60 days, and a requirement that the minister consider public comments or submissions and report back on what changes if any have been made as a result.

We understand that there is a clear process for guiding the development and posting of federal regulations, but it does not provide statutory requirements for the type of consultation we have proposed.

● (1545)

Central to Bill C-11 is the requirement for ministerial licences. Our public health laboratories already operate under the laboratories licensing act and follow routine accreditation. The proposed bill appears to create what is, in effect, a duplicate laboratory licensing regime.

We suggest that opportunities for harmonizing the licensing with existing regimes be considered.

The bill proposes that all accidental exposures to listed agents be reported federally. This runs the risk of intersecting with occupational health and safety requirements, and we recommend that overlap with those existing requirements be examined and eliminated.

As others have noted, the requirements for security checks could provide for very onerous burdens. We already have security checks in place for a number of individuals who are working in our laboratories who have access to certain types of pathogens. These security checks, as you have heard, could have a significant impact on training and students, as well as on our ability to bring in additional staff when we have to add surge capacity during an outbreak.

We recommend clarification of the requirements for security clearance for different categories of workers and an assurance that there will be appropriate processes for circumstances such as we have described.

Clause 38 of the bill spells out an extremely broad ability for the minister to order an applicant to disclose personal information. Central to our concern is the excessive breadth of this requirement and the lack of a reasonable test for the information that is being requested. We would like to see much greater detail in the bill regarding these powers.

In conclusion, we support the spirit and intent of Bill C-11 but feel that there are far too many unanswered questions at this stage.

We note that in the United States, following publication of similar legislation, many laboratories simply chose to stop working with listed pathogens rather than face the hassles and costs of complying with the legislation. The net result was diminished capacity to face public health threats.

We believe that an approach to biosafety and preparedness should be comprehensive and engage the laboratory and scientific community. We support the proposal by Dr. Peter Singer, who appeared before you last week, for a comprehensive assessment of Canada's readiness for bioterrorism through the Council of Canadian Academies.

In summary, the proposed bill creates what could become a significant duplicate inspection and compliance regime that imposes administrative burdens and costs.

Thank you for this opportunity to share our concerns and recommendations. We look forward to your comments and questions.

● (1550)

The Chair: Thank you very much, Dr. Goel.

We'll now go to Dr. Michael Hynes, from the University of Calgary.

Dr. Michael Hynes (Professor, Department of Biological Sciences, University of Calgary): I would like to thank the honourable members and the committee for giving me an opportunity to speak today. I'm here on behalf of the Canadian Society of Microbiologists, of which I am the president—that's an elected office, and it just happens to be me this year. This is a society of about 400 to 500 members that represents all microbiologists in Canada who are willing to join. They're primarily research microbiologists in universities and government labs, but we do have some clinical microbiologists who are members as well. We do liaise quite a lot with some of the other societies in Canada, including the Canadian College of Microbiologists, which is a professional accreditation organization, so they've given me some feedback as well.

I'm a professor at the University of Calgary. My own research is in microbial genetics. I don't work with pathogens, so this legislation does not affect me personally. I don't have any axe to grind. I have based my comments on what I think is going on and largely on responses to this bill from my members. Usually when you send out a request for input from members in a society such as mine you get nothing. I've been overwhelmed with the response I've received about this bill, by e-mail comments, phone calls, conversations. This was also reflected last year at our annual general meeting; we've devoted a considerable amount of time to the discussion of C-54.

People are concerned because they don't really understand the necessity for this legislation in its proposed form. The track record of the microbiology community in Canada is excellent. Existing biohazard guidelines that are in practice for university and government labs are respected and they seem to be working, so there is a lot of concern within our society. Most of this arises from the fact that the level two containment you find in the guidelines from the Public Health Agency of Canada state explicitly that organisms in this group pose little risk to the community, and thus many members of our society feel there's no need to legislate to include them in any toxins and pathogens act.

I got lots of comments about this. Perhaps the most apposite is from one scientist who said I'd be much safer camping in his lab for two weeks than going to a hospital because I'm much more likely to get a serious infection in a hospital. Really, it's the inclusion of level 2 pathogens in this bill that has people concerned.

A second major concern is that E. coli is included in the bill on the list of level 2 pathogens, when under current guidelines, only pathogenic strains of E. coli are listed. This is very important to our members because almost everybody uses E. coli to do genetics experiments. This applies not only to microbiologists but to anybody who's doing anything involving gene cloning. The types of E. coli strains that are used for gene cloning are non-pathogenic; they've been recognized as non-pathogenic for many years, so some statement should go into this bill saying that not all E. coli is level 2.

There's additional concern within the society about the costs to research and delays in research and in hiring students, which may be occasioned by a strict adherence to the terms of the bill, as opposed to the feedback we're getting from the Public Health Agency of Canada. There's a lot of concern that it may be very difficult to employ foreign students and post-docs because it's already hard enough for them to get visas. If we have to go through security clearance for them, there may be issues with that.

There's a lot of concern about the disconnect between the language of the bill and the much more reassuring tone we get from officials of the Public Health Agency of Canada. When they speak at information sessions, they are addressing the issues very well, but all the documents they give to us say this is proposed, it's not fact. We'd like to be reassured that what they're talking about is what's going to happen.

Some of the other questions from our membership relate to: how does this licensing system increase safety and security over the status quo via safety regulations that are used in universities and government labs? The list of microbes on the schedules is presented as species when we as microbiologists realize that it's the strains that are pathogenic. Many members of the species on those lists are non-pathogenic; they don't pose any threat to human health. Of course, with the constant reclassification of micro-organisms, things could be lumped in with another species when in fact they don't pose any threat.

● (1555)

There was a question about whether the licences will be awarded at the level of the institution, the group, or the individual, because the legal definition of person includes all those, and the bill just talks about persons. There was a suggestion it would be more effective to license facilities rather than individual researchers. We don't understand what the conditions for awarding licences to carry out work with pathogens might be, or whether there will be an appeal process if your request for a licence is turned down.

The cost of the licences is not addressed in the bill itself, whether that will be borne by the researchers or by the government. The Public Health Agency preliminary documents suggest there will be no cost, but we'd like to be reassured of that. We don't know how this is going to affect undergraduate education in microbiology laboratories, laboratory space shared between researchers, some of whom are working with pathogens and some of whom aren't. How will custodial staff have access to labs? Will they require security clearance as well? These are on the whole list of questions I'm getting back repeatedly from my membership.

The eligibility for security clearance is a major issue. That could quite easily become a basis for some human rights problems, as we see it. We don't know who the inspectors will be, how they will be trained, and how they will carry out their tasks.

I'd like to draw the committee's attention to the international journal, *Science*, which on March 6—last Thursday—published a brief article about Bruce Ivins and anthrax. This is the person who is believed to have been responsible for the anthrax attacks in the United States a few years ago. Some of the things said in that article really hit the nail on the head as to the concerns of members of my society. For example, they're suggesting that the security risk assessment in the States is going to take 45 days. We frequently have visiting scientists from other countries who are only spending a month in our lab. We could just never get them in, and maybe it wouldn't be worth going through this process for such a short period.

The security risk assessment in the U.S. has suggested to exclude persons with substance abuse or mental health problems. That seems to be an issue to me. This is the real scary one: being a citizen of a country the U.S. deems a sponsor of terrorism. Now, this could in fact be used against many Canadian citizens who hold dual citizenship and happen to come from one of those types of countries.

The last thing I would like to mention is that there could potentially be a health risk associated with a risk assessment licensing procedure if the delays are too long. If a diagnostic lab, in the face of an emergency like SARS, has to hire additional personnel or is short of personnel and has to have them in place to do the work, and this bureaucracy interferes with that process of hiring, this could actually backfire in terms of public health.

That is all I have to say. Thank you for your attention. I'd be happy to answer any questions in French or English.

The Chair: Thank you so much.

We'll now go to Dr. Descoteaux. We look forward to your presentation.

[*Translation*]

Dr. Albert Descoteaux (Professor, Institut Armand-Frappier, Institut national de la recherche scientifique): First, let me thank you for giving me the privilege of coming to share with you the concerns of a number of my colleagues and myself with regard to many aspects of Bill C-11.

I am a professor and researcher at the Institut Armand-Frappier. Most of the research and teaching activities at our institution are in virology and microbiology. I am also deputy director of the Centre de recherche sur les interactions hôte-parasite and I hold a Canada Research Chair in infection and immunity. I have more than 25 years' experience in microbiology research.

My interest in Bill C-11comes initially from the classification of micro-organisms in the previous version of this bill, Bill C-54. In it, the parasite that I work with, the Leishmania parasite, was classified in group 3, a glaring error. It mobilized the research community that works with the Leishmania parasite, because of the potentially disastrous consequences that this could have on our research work. Regrettably, there had been no consultation with the researchers involved on the reclassification of this micro-organism, and a number of others. It seems that it was done in quite an arbitrary way. Of course, I cannot make that assumption, but it seemed to be so.

A number of corrections were made to the classification of micro-organisms and toxins in Bill C-11. But problems remain, as Dr. Hynes has indicated. Let me give some examples. Viral strains, such as VSV, are classified at level 3, whereas several strains are modified for the laboratory and used with animal models to understand how they cause infection. Mycobacterium bovis, the BCG vaccine strain, is classified in level 3 in this bill, yet one third to one half of the world's population has received the BCG vaccine. This vaccine is currently used to treat certain cancers, such as bladder cancer. Imagine doctors having to go to a level 3 facility to treat their bladder cancer patients with BCG injections. It would be absolutely ridiculous. Escherichia coli was also mentioned.

I would also like to mention toxins briefly. People seem to be very afraid of toxins. But a toxin called botulinum is used to treat wrinkles and some spasms; the common name is Botox. In humans, it is not really very dangerous. Another interesting thing about bacterial toxins in research is that molecules of microbial origin target molecules in our cells in very specific ways. So these toxins become essential tools in studying how a cell works. In cancer, in neurology and in immunology, for example, toxins are frequently used to block cell functions. If toxins became impossible to obtain, or extremely difficult to keep, a good deal of research in those areas would have to be abandoned, or would become very difficult.

As for basic research, that is, the kind of research in microbiology and the fight against disease that a number of my colleagues do, and I include myself, we know that it is essential if knowledge is to move forward. It allows us to understand the interactions between microbes and their hosts, including humans, the pathogenic processes and the immune responses that humans generate against these micro-organisms. Knowledge like that is essential in order to develop vaccines, treatments, diagnostic tests, and so on.

The current version of this bill can potentially have negative consequences. What consequences can over-restrictive legislation have on microbiology research? It could mean reducing or abandoning research on some micro-organisms because of the administrative complexities and the lack of adequate infrastructure. For example, if a researcher in an institution is working with a level 1 organism that is now classed as level 2, he no longer has the required infrastructure, which is very expensive. Is he going to continue his research? Where is he going to get the money to upgrade his facility? The same happens with pathogens that move from level 2 to level 3.

Costs go up for the research institutions and for the researchers who are funded by the Canadian Institutes for Health Research, for example.

● (1600)

Who is going to pay for the oversight mechanisms, the permit applications, the administration? It is all very well to impose constraints, though they seem excessive to me, but who is going to pay for them so that the research does not suffer? Let us not forget that most research in health and microbiology in Canada is funded by the federal government. If this bill is passed in its present form, there will be less return for each grant dollar.

It was said earlier that research requires the free exchange of information, knowledge and reagents. By "reagent", I mean exchanging microbial strains, and I am not alone. if the rules are too strict, it can interfere with researchers' ability to exchange and obtain the reagents they need to pursue their research. How are we going to address those questions? The bill does not really make it clear. Ultimately, it is the fight against infectious diseases that may be affected by this bill because of the influence it has on the potential for research in Canada.

I would also like to talk about the negative impacts of overly restrictive legislation on the training of highly qualified people. By that, I mean the students in our universities and colleges. As director of the doctoral program in virology and immunology at my institution, and as a professor who teaches microbial pathogenesis, this concerns me greatly. It is crucial to ensure that the next generation of microbiologists in Canada is properly trained. That is done by having them work with micro-organisms.

These highly qualified people will be needed in order to staff our hospitals. These are the diagnosticians, the people who take samples, and so on. They are in research institutions, private or governmental. They are in biotechnology and pharmaceuticals. In the food industry, they are in quality control departments; we have heard plenty about contamination problems in that industry. People have to be familiar with micro-organisms. So we have to train people so that, for example, they go into government laboratories or into teaching.

In Quebec, we train laboratory technicians at college level. They have to learn how to recognize and work with micro-organisms. A good microbiologist can tell the strain of a microbe by smelling it. He can see the shape of a colony in a Petri dish. If we do not give them the ability to do that, or if it is too difficult to have practical courses in schools, universities and colleges, it is going to be very difficult to train the next generation of microbiologists.

We must make sure that the legislation does not prevent students and trainees from getting into research laboratories, or prevent them from learning by working with micro-organisms. You do not become an auto mechanic without ever rooting around inside an engine or a transmission. It is the same in microbiology. You have to be able to play with these micro-organisms in order to really get to know them.

The greatest dangers from infectious disease that Canadians are exposed to are likely to be in contaminated water and food, which are, in fact, often used to justify this bill. Think of Walkerton, think of the listeria crisis, and so on. You can also go to a restaurant, eat something suspect and get food poisoning, but a bill like this is not going to prevent that. The problems there are negligence, inadequate maintenance, poor practices in hygiene or cooking. Nosocomial infections, the ones you get in hospital, are associated with hygiene problems, as are outbreaks of C. difficile. We tackle epidemics such as flu, SARS and legionellosis with appropriate public health measures that allow us to limit and isolate the outbreaks. Canadians will not become safer overnight, or be in less danger from infectious diseases, because of restrictive legislation.

In my opinion, this bill cannot be used to pretend that it is preventing this kind of everyday hazard. I will end by saying that the vast majority of microbiological research in Canada requires micro-organisms in containment levels 1 and 2.

● (1605)

Because they pose a very low risk and because it is unlikely that they would be used for bioterrorism, micro-organisms in schedule 2 must, in my opinion, be removed from Bill C-11.

Thank you for your attention.

[*English*]

The Chair: Thank you so much for your comments.

We're going to go into the first round of questioning right now. It will be seven minutes per party.

We'll start with Ms. Murray.

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

Thank you for those detailed and very knowledge-filled presentations.

One thing that I am trying to understand with this legislation is the problem this bill is a solution for. Can you give me a snapshot of the national or international events that would cause us as legislators to say that we need these new rules, that this is a good thing, and that we're dealing with a problem that people agree exists? Can you comment on that?

The Chair: Who would like to take on that question?

Professor Hynes, I noticed you looking as though you were anticipating this.

Dr. Michael Hynes: I'm not sure if I'm the best qualified person to answer that.

There obviously has been concern about the possibility of micro-organisms being used for bioterrorism. Some of the precedents for that are the suspected use of anthrax and other agents in the Iraq-Iran war. There was the incident of the anthrax attack in the United States through the mail, which allegedly was carried out by a Department of Defense scientist employed by the government, who had passed through security checks to get his position.

There is again a question as to what measures we can really introduce that would prevent something like that. I suppose there is a general sentiment because of things like SARS and Walkerton, that there's concern in the public about microbial infection, which is not necessarily going to be addressed by this act at all.

I think part of the reason the Canadian government wants to address this is that the American government is doing it, and we do have to walk in step with our neighbours on the same continent with whom we share a long border. There is also the concern that small companies and things like that would not necessarily be observing the currently existing biohazard guidelines. They're not obtaining their funds from national research councils like CIHR or NSERC, and therefore they're not subject to the biohazards certification to carry out that research. I think there is a rationale for trying to bring everybody to the same level playing field if they're doing microbiology research, to make sure they're all following the same rules. We respect that in our society.

● (1610)

Ms. Joyce Murray: So to add to that question, are there any aspects of the scheme that will create a standardization that will actually save your organizations time and effort in setting procedures for handling and storing of biohazards and for training?

Dr. Albert Descoteaux: Maybe I can answer that question.

Concerning level 3 and level 4 pathogens, there are already a lot of regulations. I don't think that adding this criminal aspect would help in deterring somebody determined to cause a bioterrorism act.

I think somebody like the person who was responsible for sending anthrax to the member of Congress in the U.S. was a person who knew how to work with anthrax, who had all the security clearances. If somebody becomes crazy, you cannot do anything about that. By making a law even more repressive, you will not be able to solve this problem or address this issue.

Ms. Joyce Murray: Ms. Sarabia, you mentioned that the bill has to strike a balance.

The Chair: Can I interrupt for one moment?

I think Dr. Low wanted to make a comment following that—did you, Dr. Low?—just to further answer Ms. Murray's question.

Dr. Don Low (Medical Director, Public Health Laboratories, Ontario Agency for Health Protection and Promotion): Yes. Thank you.

It's really critical that we separate biosecurity and biosafety. There is concern about biosecurity so that you know there's control over the pathogens you are working with, and those fall into risk groups 3 and 4. Biosafety is something all of us, as medical microbiologists and technologists and technicians, are trained to do and are inspected and licensed to do. It deals primarily with level 2 or risk group 2 organisms.

I myself am not aware of any event that has occurred that this bill would prevent. I'm not aware of any event that's been published in the literature or of which I have personal knowledge in which a level 2 organism has escaped from a laboratory and caused disease. We have outbreaks with level 2 organisms all the time, but they do not originate in a laboratory. We have to keep biosecurity and biosafety separated in the discussions.

Just to come back to the biosafety issue and these restrictions, remember that many if not most of the laboratories in Canada are in small hospitals and are intermingled with other departments, such as biochemistry and hematology, and technologists are cross-trained, so these kinds of regulation are going to affect not just microbiology but laboratory medicine across the country.

● (1615)

Ms. Joyce Murray: Do you believe there is a significant risk of harm if the government were to withdraw this bill and consult with provinces and territories as equal partners and with the industry in a way that was considered sufficient, and then reintroduce the bill afterwards? Would there be major risk to the public from a pathway like that?

Dr. Don Low: No.

Dr. Vivek Goel: The answer is no, because as has already been clearly indicated by the Public Health Agency of Canada, they recognize that they're going to have to take quite a bit of time to do the consultations on the regulations. They won't be able to implement the bill, if it is passed immediately, until they go through that.

From our perspective, it would be far better for them to go through that process and then clarify some of these issues in legislation where possible, and publish the draft regulations as they put the legislation through. I don't think anything harmful would happen in the meantime.

The Chair: Okay.

We'll now go to Monsieur Malo.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): Thank you very much, Madam Chair.

Before I turn to you, my dear witnesses, I am going to talk to my colleagues. So, first of all, thank you for being here with us today.

Ms. Murray asked the witnesses a clear question and they all gave the same answer. All my colleagues will agree with me that, with the exception of the officials, of course, all the witnesses who have appeared before us were of the same opinion. None of them said anything to the contrary. They are all convinced that this bill contains unanswered questions that significantly affect the way in which they do their work. I feel that we, as members of Parliament, would be misguided if we did not heed the unanimity from the witnesses and react to it in a meaningful way.

That said, I would like to pick up on an aspect of the discussion that I had never heard before. Mr. Goel said that similar legislation had been put in place in the United States and that it put an end to a number of research projects. I found nothing definitive in the notes provided by the Library of Parliament. It would be interesting to find out more about that. When we get comparisons from outside the country, in fact, we generally study them right here at the committee. If you have any more information about the matter, I would like to hear it right now.

[*English*]

The Chair: Who'd like to comment on that?

Dr. Goel.

Dr. Vivek Goel: I'll be happy to forward the publication to the clerk. There was also an article in the *American Journal of Science* in 2004, where they reported on the Patriot Act, which has provisions similar to what is in Bill C-11. The Centers for Disease Control estimated—and I don't have the exact figures—the number of labs they expected to be working with a list of pathogens, and only about a third of those labs actually applied for a licence. Many of the universities, including major institutions like MIT and Stanford, rather than choosing to continue those lines of research, just said they would not allow their faculties and graduate students to work in those areas.

So the net result is that the ability of the nation to be prepared and training people who are working with those types of pathogens gets diminished through this.

I would also note that the U.S. legislation primarily applied to level 3 and level 4 pathogens. So they did not have the kinds of restrictions on level 2 pathogens that could be contemplated with this bill. Indeed the impact might be even greater.

The type of study Dr. Singer has proposed, as described to you last week, is precisely what the United States did after that through the Institute of Medicine and the National Academy of Sciences. They had a comprehensive assessment where the Centers for Disease Control, the National Security Agency, and the academic and lab communities were brought together to look at the most effective way to strengthen biosecurity and biosafety. I think that's really where Canada should be headed as well.

● (1620)

[*Translation*]

Mr. Luc Malo: Thank you for pointing out to us that, when it comes down to it, all the questions raised by the researchers who have testified here are perhaps due to the fact that the agency did not make use of a preliminary regulatory framework. If you could have participated, helped to draft it, I feel that all these questions might not have come up at all. You would have had the answers well before appearing here today.

Mr. Goel, Mr. Descoteaux, you brought up the question of research being abandoned. Mr. Descoteaux, you even went a little further in suggesting that, in economic terms, each dollar invested would be worth clearly less than it is today.

Can you give us more details about that?

Dr. Albert Descoteaux: I briefly mentioned inadequate infrastructure. To establish a level 2 containment laboratory, you have to buy the proper biological safety cabinets. If you do not have them, they will cost you $20,000. Where is that money going to come from? Building and maintaining a level 3 containment laboratory is extremely expensive. It must also be certified. As to all the administrative requirements, if the researcher does not look after it all himself, the university or institution has to hire people to do it. Those costs all add up, but nowhere does it say who is going to pay them.

I get a grant of $120,000 per year from the CIHR, but I do not know what portion of that grant will be used to take care of the requirements of the bill. Will it be 10%, 20%? I do not know. I cannot give you exact figures because we have not faced the situation yet. Whatever it is, I know that laboratory equipment is expensive and it is not at all clear how it is to be acquired and paid for.

[*English*]

The Chair: Thank you so much.

I will now go to Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you very much, Madam Chairperson.

Thanks to all of you for your very informative presentations.

I'm not sure that having this bill removed entirely and starting again is in the cards. Unless we hear from the government, we may be working within this legislation. I suppose that's something we can hope for and ask for, but if we can't start again, what's the next best way to approach your concerns? That's a general question to all of you.

More specifically, if we move to amend this bill to remove its application from level 2 pathogens, do we get to the crux of the problem you're raising? What other amendments would you recommend?

Maybe each one of you could answer.

The Chair: Go ahead.

Dr. Vivek Goel: Sure. Certainly, to be fair to the Public Health Agency of Canada and the government consultations, they have issued a document on the draft regulatory framework. I think the concerns have been expressed.

The document starts by saying it's for discussion purposes only and it's not to be construed as being a policy statement. Then there are many words like “may” and “would” or “could”, as opposed to saying this is what the regulatory framework would actually look like.

First of all, if the legislation goes forward, we would like to be clear that as this gets developed, we will have an opportunity for—

Ms. Judy Wasylycia-Leis: Could I just stop you there for a second? When did you receive this draft regulatory framework?

Dr. Vivek Goel: I have a copy dated February 2, which I received this morning.

Ms. Judy Wasylycia-Leis: Has this committee ever received it? I've never heard of this, so this is—

A voice: I have a copy.

The Chair: Could I just answer that question?

Ms. Judy Wasylycia-Leis: Sure.

The Chair: It's on the website apparently.

Ms. Judy Wasylycia-Leis: One would have thought that the government, in presenting this legislation, would have given us all the relevant documents.

● (1625)

The Chair: Apparently you can go to the website. Is that—

Ms. Judy Wasylycia-Leis: Well, that's fair enough, but it's not included officially from the representatives. It's unfortunate.

Go ahead. I'm sorry to interrupt you.

Dr. Vivek Goel: So certainly I think we'd like to have a commitment to be able to work together on this.

On the second point, I think my colleagues can speak to the removal. Clarity on what would actually be the framework for level 2 would be very significant. That's where quite a bit of the concerns are about the impact it's going to have on operations.

In terms of what's left, from our perspective, the other remaining area of concern is for levels 3 and 4. It's really level 3 that's of concern to everyone else because the only level 4 is the government lab in Winnipeg. We still have this conflation of biosafety and biosecurity, and measures for biosafety, which are obviously very significant and very important, are attached to a bill that criminalizes lack of compliance.

If someone working in the labs is not compliant with the legislation in a strictly biosafety framework, you try to work to improve people's quality and so on, but this legislation hits them over the head with the threat of criminal sanctions, including jail sentences. It's the criminalization of a set of activities that really supports laboratory practice, whether it's in clinical practice or in research.

The final piece is around the minister's authority to collect and share information. Again, within the bill as drafted, it allows the minister to define, in the minister's own opinion, whether the request is within the purposes of the act. There's no reasonable test applied. Then it allows for the sharing of that information with other parties, potentially including foreign governments, without the consent of the individual from whom that information is drawn.

Ms. Judy Wasylycia-Leis: I'd like Mr. Descoteaux to answer my question and add to it. I want to get a clear indication from everyone that, as a minimum, you would be in support of an amendment that would remove any application of this bill to level 2 pathogens. That's number one. Beyond that, are there other amendments? If we're working with this bill, what can we do to make it work?

Dr. Albert Descoteaux: Concerning the level 2 pathogens, if you consider the risks associated with working with these pathogens, the risks or the remote possibility that terrorists would use them to cause harm, and then you consider on the other hand the constraints—financial, etc.—on researchers working on level 2 pathogens, it's not worth it. The best solution is just to remove that list of pathogens from the bill.

Nobody disputes the fact that you need to protect people who work with level 3 and 4 pathogens. Just protect the people themselves, their co-workers, the people in the same building, and then the people outside the building. Nobody disputes that fact.

Ms. Judy Wasylycia-Leis: So completely remove the criminal sanctions under this bill?

Dr. Albert Descoteaux: Well, I think it's a bit exaggerated, but—

Ms. Judy Wasylycia-Leis: Do you think it's an overreaction or a way to create the facade of reacting to bioterrorist threats in the wake of 9/11, as opposed to a real solution? Some of the witnesses we've had have suggested that the real dangers, in fact, are these pathogens and toxins yet to be developed and that we don't even know what's out there and what could be done.

Given the fact that at the same time we're cutting back on research that might get us the answers to some of those questions, I'm just wondering if that's why. Or am I extrapolating too much here?

Dr. Albert Descoteaux: No, but if you look at the possible sentences and fines for not complying to specific rules.... If you work with a level 2 pathogen and you don't comply, you can be fined and go to jail. Compared to somebody who is caught drunk while driving, it's a clear imbalance between the potential impacts on the population. I think it's a bit exaggerated.

Ms. Judy Wasylycia-Leis: Michael, Alicia, or Don, do you have any comments?

Dr. Michael Hynes: The membership would be very happy to have level 2 pathogens removed from this act—at least for now—even if that reference were to be replaced by a statement that all work with pathogens should be subject to guidelines generated by PHAC. That would be fine in the act. We'd wait to see what those regulations were, and we'd consult with the agency. What we've been receiving in the form of these documents at information sessions looks fine to us, but they're full of “might”, “may”, and “probably”, and we don't know for sure.

So for now we'd be very happy with the removal of level 2 pathogens from the act, and maybe the addition of a clause that says that all work should be regulated by regulations.

● (1630)

The Chair: Thank you, Professor Hynes.

We'll now go to Dr. Carrie.

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

I want to thank each and every one of you for being here today.

What I'm hearing from you is a little frustration about how this has been rolled out. I do understand that PHAC did hand out the regulatory framework at the consultations. It's a public document. It's the same framework that was sent out to the members. You did receive it today, because it was mentioned I think by previous witnesses that this was an issue.

You mentioned, Dr. Hynes, that you liked the regulations, or you accepted them, but that they're filled with all of these “mights” and “mays”. You've come up with some points that I actually brought up in the briefings. I'm not a drafter of regulations and I don't know why they think of things in certain ways, but I do believe that the reason they put the “mights” and “mays” in is that they do want to negotiate and consult to make sure they get it right.

One of the points I wanted to bring up, because there does seem to be some confusion perhaps that the department didn't make this evident, is that there are certain regulations put on the laboratories who import. When they import into this country—and I'm not sure if you're aware of this—there is a different regulatory framework than when one is just a domestic lab.

So the idea of this legislation is to bring the domestic labs up to that level, because you could potentially have a lab that takes in Ebola. This would be an extreme situation, and it might not exactly be relevant, but when labs transfer it domestically amongst the labs, there's no regulatory framework letting the government track where the bad ones are. So that is the rationale given to me for why we need to bring this up to a level playing field.

You also mentioned the language of E. coli, how there's pathogenic E. coli and then there's non-pathogenic E. coli. When talking to the drafters, I brought that up, and they said to me that by definition, it was an act to promote safety and security with respect to human pathogens. So if one strain of E. coli is not pathogenic, it wouldn't be caught under this act. Okay?

So, curiously, regarding some of the problems or concerns that you're bringing forward, it appears they might be laid to rest somewhat if we had really good explanation for them.

But I do want to ask, if we were able to make amendments or clarify, for example, the E. coli, would that start to alleviate some of your concerns? If we said non-pathogenic E. coli is over here, instead of here, would that alleviate some concerns?

Dr. Michael Hynes: Right now, it reads:

> "human pathogen" means a micro-organism, nucleic acid or protein that
> (a) is listed in any of the Schedules

And one of those schedules includes E. coli.

If you interpret that literally without recourse to a set of regulations that explain things otherwise, it says E. coli is a pathogen. It doesn't matter which one.

Mr. Colin Carrie: I get exactly what you're saying, but I'm trying to explain where they're coming from here.

Would you be supportive then if the Public Health Agency established an expert advisory group to review the schedules as needed, based on the scientific evidence, and to advise the Minister of Health on any changes that should be made to those schedules, by adding or removing or reclassifying a human pathogen or a toxin? Would you be supportive of that?

Dr. Michael Hynes: I think it would be great to have such an advisory committee. I'm sure the regulations will come out fine after PHAC goes through them and consults with people. It's just that there's an issue, especially among the more vocal members of my society, that they do not like being asked to accept on faith an act that has definitions that go one way, with the promise that the regulations will make those definitions less draconian in the future. We don't know what's going to happen in the future that might make the regulations not come out the way they're being promised in these preliminary documents, in which case we would be faced with severe problems, as Dr. Descoteaux has outlined, in terms of costs and people leaving the field.

So accepting something on faith is not something that everybody is willing to do.

Mr. Colin Carrie: That may be a very wise way of thinking, I think.

Would you be supportive of a phased-in approach, with the regulatory changes?

Dr. Michael Hynes: I think so, yes. We'd deal with the severe issues of levels 3 and 4 first in an act, and then clean up the other stuff afterwards. That would make sense to me.

● (1635)

Mr. Colin Carrie: Okay.

Dr. Descoteaux, you mentioned that you're someone who does work with Leishmania. Originally, with Bill C-54, I guess it was in risk group 3, but with some consultation they moved it down to level 2.

How did that process go? Was it onerous, or did you find that they weren't listening to you, or was it a pretty good process?

Dr. Albert Descoteaux: The classification to schedule 3 was a big surprise to all of us working on Leishmania in the country. There was a big mobilization. There were just about 12 labs in the country working on Leishmania. After our contact with Health Canada and Mr. Hynes, whom I just met here today, they went back to their papers and found that there was no reason to classify Leishmania as a level 3 pathogen. That's something we had told them before, but they had to do the search and they realized it.

You wonder why they classified that pathogen as level 3. What was the reason?

Mr. Colin Carrie: But they did listen to you and changed it, right?

Dr. Albert Descoteaux: Yes, they did, which is a good thing. We are very happy that they listened. But then you wonder about the other pathogens. I don't know; I did not do the work for the other people.

Mr. Colin Carrie: Could I ask all of you for an opinion here? You talk about risk level 2, and when you're talking about it to the committee you make it sound as though these pathogens are not "dangerous" or may not cause problems and that they should be removed; there were some who brought that out. But a while back in the States somebody took a pathogenic type of E. coli and sprinkled it on a salad, and a lot of people got sick. I believe C. difficile is classified as risk 2, and we hear that people are dying of C. difficile.

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

Who would like to answer that question?

Dr. Low.

Dr. Don Low: In those examples, it's the host, not the lab, that is the risk. We all carry those organisms to some extent on our bodies, and it's when the wrong set of circumstances occur that it's allowed to cause disease, whether it's from taking an antibiotic and getting C. difficile colitis, or whether it's from a urinary tract infection due to E. coli. Those originate in the host, not in the laboratory.

The Chair: We're about to go into the second round now. If it's the will of the committee, I would like to ask a question.

Is it okay if I do that?

Do provincial occupational health and safety laws make it mandatory for those using risk group 2 pathogens to comply with the laboratory biosafety guidelines? Could anyone answer that for me?

Professor Hynes.

Dr. Michael Hynes: I don't think I can answer that question.

The Chair: Dr. Goel.

Dr. Vivek Goel: I can't speak to the specifics, but I would expect it's going to vary by province. In Ontario the Occupational Health and Safety Act already provides for some of these provisions.

The Chair: Are there any other comments on this? Is there any other knowledge?

Thank you.

We'll now go to round two, and we have five minutes per person.

Dr. Bennett is first.

Hon. Carolyn Bennett (St. Paul's, Lib.): I must say that I, like my colleagues, find this pretty depressing. If I were the minister, I'd be furious that you hadn't been consulted and listened to. This idea that "we'll fix it in the regulations" is just not good enough. Tough cases make bad law. Every one of you, as Luc has said, is concerned that either you weren't consulted or were not listened to. Certainly, when you have both Ontario and B.C. asking "What are you doing?" and you're hearing stories that harmonizing with the United States means that big universities decide not to investigate things, this is very worrying.

There is something in the bill that's important about intentional release, I guess. There's probably something in the bill about our knowing where the bad stuff is and being able to track it. But other than that, in terms of what Joyce has said, I wonder whether the government should be asked to do the consultation first and then come back with government amendments to see whether or not this is workable, including taking out the level 2s and any of the important suggestions that should have been made at the consultations and should have been reflected in the bill to begin with.

David Butler-Jones himself has one of the most important phrases: "Oh, my God! We have to do something. This is something. Let's do that." This is a "this will do" kind of bill. I feel embarrassed personally that after the briefing I had from the department I spoke in favour of this bill. It makes us all look like fools. I wrote "citizen engagement" into the job description of the Chief Public Health Officer. What happened? We haven't had one witness say this is a good bill.

I think Joyce's question about the problem we're trying to fix is very narrow. We have this big fire hose going at it, which has all these unintended consequences we didn't know about until we heard from the witnesses. The discussion paper that you find reassuring concerning the possible regulations is a good sign, but I guess I would like....

We have a dinner with the minister tonight as a committee. I don't think she'll be very happy with the way this bill is going. I'm sure it's something she had been persuaded was a no-brainer and would just go through. But now we have all of this. I think the minister has been seriously let down.

I would hope that the government would decide to do something itself. I don't think we as the opposition should be fooling around with amendments in some sort of patchwork quilt to try to fix this sow's ear. I don't think that's our job, frankly. We have some amendments about the regulations coming back and some amendments about advisory committees, but what I think we are taking from this afternoon is that it's a mess. Even the schedules are a mess.

I don't know what to say, other than that if you were consulted—

● (1640)

The Chair: You only have ten seconds to say it, Dr. Bennett.

Hon. Carolyn Bennett: Were you consulted, or did the government not listen to what you said?

The Chair: We only have about 30 seconds left.

Would someone like to make a comment?

Dr. Goel.

Dr. Vivek Goel: I think the Public Health Agency of Canada characterized them as information sessions. There were a number of them held across the country with Bill C-54, and then in late January or early February there were three meetings across the country prior to the re-introduction as Bill C-11. Certainly this document was tabled, many of the issues you heard about today and last week were raised, and the response was almost always that it will be dealt with in the regulations.

So I would characterize those, as they have, as information sessions. They were not consultations.

The Chair: Thank you, Dr. Goel.

Ms. McLeod.

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

With all due respect, I disagree with my colleague. Most of the witnesses we've heard believe that this bill is an important one, that we should be moving forward, and that there are some issues they would like to see addressed where they have concerns. To characterize it as a mess is perhaps overstating some issues that could perhaps be worked out through the committee process.

We've heard one suggestion from Mrs. Wasylycia-Leis about risk level 2 pathogens. We heard from the health agency that they were really only looking at an inventory and general safety necessities around those risk level 2s. So if you had something like that written around risk level 2 that was very specific about what it would entail in the act—that it was very different from levels 3 and 4—would that not be a good approach? As you said earlier, we have many different types of labs in many different provinces with different things happening. Would that be an approach to take with risk level 2, clearly defining their interests around inventory and a few other more generic things?

I'd like feedback from everyone.

Thanks.

● (1645)

The Chair: Ms. Sarabia.

Dr. Alicia Sarabia: I would still prefer to see regulations first that address all of those issues—because they span a real breadth of different areas that affect the labs operationally—before having legislation go out. Then we could work on the regulations in partnership with PHAC.

Mrs. Cathy McLeod: Within the legislation, if we're talking about having a clause that defines it, level 2 is very different from levels 3 and 4, and it will be X, X, and X.

Dr. Alicia Sarabia: There would be lots of different specific points throughout the legislation that would refer to level 2 and how it was different from levels 3 and 4. It's not just inventory; it's authorization of folks coming into labs and maintaining lists of people who come in and out of labs. Pretty well throughout all of it you could have a question that would pertain to level 2, so you'd have to make exceptions throughout the course of the legislation. They could be minor points, but the breadth would be significant.

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

Monsieur Malo.

[*Translation*]

Mr. Luc Malo: Thank you, Madam Chair.

I would like to pick up on Ms. McLeod's comments. Everyone here agrees that the spirit of the bill is good and the remarks in the House reflected that. All the witnesses said the same thing. Dr. Sarabia said that the important thing was the balance between safety and research. I think that everyone can agree on that.

However, all the witnesses say that they are fundamentally afraid about the way in which the bill will affect their work. My colleagues on this side and I think so too, and so does Dr. Bennett. Dr. Descoteaux even talked about training. If years of work can be wiped out for want of trained staff, that is serious.

At this stage, we have no answers. I think that Dr. Bennett's suggestion is important. The government should go back and do its homework, consult, and propose amendments that would address the fears of our witnesses, the researchers and the people in the trenches. The government should come up with a preliminary regulatory framework so that these people know exactly what is intended.

What do our witnesses think of that way of going about it? If the government were to propose amendments designed to allay all your fears, including removing all the pathogens in group 2, would that be sufficient? If you had before you a regulatory framework that you could comment on before this committee delivers its verdict on the bill and returns it to the House, would that be a positive move on the government's part?

[*English*]

The Chair: Dr. Descoteaux.

[*Translation*]

Dr. Albert Descoteaux: Indeed. I do not like the word "pathogens" because, often, micro-organisms living in some nook or cranny in the environment suddenly find themselves inside a human being and cause disease. Using the term "micro-organism" is better than saying "pathogen" all the time. Removing level 2 micro-organisms from the bill would be a good step forward. It would also be a good idea to consult people who are working with level 3 and level 4 micro-organisms to make sure that they no longer have any problems.

Consulting the people in the trenches is the most important thing to do. We have to be sure that all aspects of microbiology in Canada, whether it is training staff, research, and so on, are not affected negatively by this bill. But the bill still has its good points: its aim is to protect people from potentially lethal micro-organisms.

● (1650)

[*English*]

The Chair: You have another minute.

[*Translation*]

Mr. Luc Malo: Go on, Dr. Descoteaux. You say that you do not like the use of the term "pathogen". So perhaps the bill should be amended to reflect that. You said that the micro-organisms have been classified in a way that you find arbitrary.

Why were they classified like that?

Dr. Albert Descoteaux: For example, no one has satisfactorily explained why Leishmania, which everyone in the world, including in Canada, considers to be a level 2 micro-organism, suddenly found itself on the level 3 list.

Mr. Luc Malo: Somewhere in the schedules, should there be the reasons why all these micro-organisms have been classified in one place rather than another?

Dr. Albert Descoteaux: Actually, there already is a classification in Canada. In the Health Canada web site—I do not know exactly where—all micro-organisms are described. It tells whether each is a bacterium, a protozoan, a fungus or a virus. It says what family they belong to, what pathology they can cause, the containment level needed when working with them, and so on. The bill changes some things with no justification at all and this is why I used the word arbitrary. Show me evidence to the contrary and I will stop saying arbitrary. Without that evidence, it is arbitrary in my books.

Mr. Luc Malo: Thank you very much.

[*English*]

The Chair: Thank you, Dr. Descoteaux.

We'll now go to Mrs. Davidson.

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

Thank you very much to each of our presenters for being here today. I'm not really sure where we're going with this.

Dr. Sarabia, you applauded the focus on biosafety and biosecurity and said it's very important to strike a balance so we can still advance diagnostic research and allow it to continue unimpeded.

I think you also said information sessions were held by the Public Health Agency, but none of the details were definitive at that time; it was just leave them until later. Is that a fair assessment of the information sessions?

Dr. Alicia Sarabia: I wasn't at the last information session because notice of it was given days before it happened.

At the first information session last year, more specific details were made known to us that were not reflected in the amendment of the legislation the second time around. I think we were asked if we felt more comfortable after the session. It made me feel more comfortable, but the issue is still that the legislation remains high-level, and it's sort of like buying a car without taking a test drive. You don't really know how it's going to work out in real life. That makes us uncomfortable.

Mrs. Patricia Davidson: I understand you had some concerns that medical professionals who would have to collect a sample of the human pathogen or toxin for diagnostic testing could be held responsible under this bill. That has been removed.

Dr. Alicia Sarabia: I didn't raise that.

Mrs. Patricia Davidson: You didn't have that as a concern?

Dr. Alicia Sarabia: No, because it clearly states somewhere that specimen collection is exempted.

Mrs. Patricia Davidson: Someone else stated that information sessions were held, but they didn't think there were consultations. I don't remember which one of you said that. Was it you, Dr. Goel? Can you elaborate on that?

● (1655)

Dr. Vivek Goel: Certainly. Again, as Dr. Sarabia has noted, first of all, for the last round, the notice period was very short. I think it was a matter of days before people in Toronto were told there was a session in Toronto. It consisted of a presentation, and even the Public Health Agency of Canada has characterized them as information sessions. Questions and concerns were raised from the floor and the response was that those issues would be dealt with in regulations. Consultations, in my mind, would be more of a dialogue where we would be looking at specific aspects of the document and the regulatory framework.

I think it's a good document. It's in the right direction. I wouldn't say it's there yet. I think we'd like to have that dialogue. I think the suggestion about having a formal committee—a formal process—built into the legislation that would require some form of consultative committee as the regulations were developed or amended would be a very positive step, as would a phase-in period. Start with the level 3s and 4s and continue with this process.

Mrs. Patricia Davidson: Do you see this is a bill that could move forward with some of those changes in it that you've just outlined?

Dr. Vivek Goel: I think certainly the sorts of things we've heard, if we had that kind of commitment, from our perspective, would comfort us a lot more. As Dr. Bennett raised earlier, I think the commitment to work with the provinces, because many of the issues being addressed here do cut into areas of provincial responsibility, and the cost implications.... We talked a lot about research and the impact on research, but there's also an impact on the provision of diagnostic services.

The Chair: Thank you so much, Dr. Goel.

We'll now go to Ms. Duncan.

Ms. Kirsty Duncan (Etobicoke North, Lib.): Good afternoon, everyone, and thank you so much for coming, for your comments, and for your insight.

I'd like to know if this sums up the discussion we've had. I think the initial feeling was that we need legislation around biosafety. However, over the last few days of consultation some real concerns have been brought forward, and I'll try to elucidate them.

There would be challenges regarding duplication, particularly with the provinces. Security clearances—how long they will take, their cost, and what that means in terms of workload. There is the issue of privacy, as well as taking a really close look in particular at the schedules and if we've categorized things correctly. I'm wondering if I'm missing anything. We'll add that to the list. What's clearly come out today is consultation.

I might like to suggest that if the government is willing, we can go back. There would be more consultation and then perhaps new amendments proposed, along with regulations, before coming back to committee.

I'd be grateful for your comments.

The Chair: Who would like to take that one on? Okay, Dr. Sarabia.

Dr. Alicia Sarabia: I think we've already demonstrated that we would be in agreement with that. It would just allow us to agree to something more explicit.

Ms. Kirsty Duncan: Have I missed anything in the concerns you've brought forth today?

Dr. Michael Hynes: One point might be that this is always going to be subject to whatever regulations the Public Health Agency comes up with, and those are going to change from time to time in response to different challenges. I think you need to build into this bill that those changes will always be after adequate consultation. I think there is a risk of pushing panic buttons due to political events or whatever happens in the world that leads to a very rapid change in regulations that could be extremely detrimental. Built into the act, there should be something saying that any new generation of regulations should involve extensive consultation with the community.

Ms. Kirsty Duncan: I think Dr. Goel wanted to make comments.

The Chair: Dr. Goel, you wanted to make a comment.

Dr. Vivek Goel: To answer Dr. Duncan's question, the list is certainly quite comprehensive. The one other area that I would suggest also be examined is the impact on costs, both for research organizations as well as diagnostic labs.

● (1700)

Ms. Kirsty Duncan: Thank you.

Dr. Alicia Sarabia: We understand the security clearances apply to level 3 and level 4 personnel, but even in the level 2 labs, my understanding is that explicit lists of folks coming in and out of labs will be required. That would be quite a challenge for many facilities to manage.

There was another term. The way of describing it was giving folks authority to come into the lab, which is not the same as maintaining specific lists with names. If we could consider changing the wording around that, it would be helpful.

Ms. Kirsty Duncan: Thank you.

Can I ask a question on how the split we're making between level 2 and level 3 compares to what's happening in the U.K. and the United States?

Dr. Don Low: It's pretty similar. Again, you have to be careful whether it's biosecurity or biosafety. A level 3 organism like microbacteria in tuberculosis is a biosafety issue; it's not a bioterrorism/biosecurity issue.

Ms. Kirsty Duncan: It's a biosafety issue. How does it compare with the U.S. and the U.K.?

Dr. Don Low: It's probably pretty equivalent.

Ms. Kirsty Duncan: Are there any changes?

Dr. Don Low: I wouldn't be able to answer that.

Dr. Alicia Sarabia: If I could speak to the point I was making about organisms within one risk group like level 3, perhaps they need to be treated differently if biosecurity is the big concern. MTB, the agent of tuberculosis, is not the biosecurity threat that bacillus anthracis, the agent of anthrax would be. So drilling down on that kind of differentiation might be....

It's hard, I'm sure, to put that into legislation.

The Chair: Thank you, Dr. Sarabia.

We'll now go to Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you very much.

Why do you think they brought forward this proposed Bill C-11?

Dr. Don Low: It might have been a post-9/11 concern, and as a result of the Patriot Act in the U.S.

I think there was also a concern after SARS, that we really didn't know what labs had the virus and where they were in the country. The concerns were raised that we really weren't tracking pathogens that do pose a threat. We saw in Asia, in laboratories working with this SARS organism in particular, where there were accidents that occurred and the virus was released into the community.

There is good intent here. I think everybody agrees with that. It's the lack of consultation.

Ms. Judy Wasylycia-Leis: I think it was Michael, or Dr. Goel, who said the U.S. is experiencing the problems you've identified that could happen here, which is research not being carried out that is necessary and important but too restrictive under this kind of approach.

Is it possible there's another agenda here, that is, part of the whole continental integration approach between Canada and the United States to harmonize at certain levels and use 9/11 as the excuse to do that and to perhaps control the research in a certain area for national security purposes?

I'm trying to understand the reasons for all this. We've had no incidents. No one talks about serious problems, other than lack of coordination between labs and different standards and levels. We haven't had a huge issue. This came out of the blue for the committee and the academic community, and there are lots of concerns.

I am trying to understand. What happens if we try to get the government to pull it back or slow it down or whatever? What is the real motive behind it all? Does anybody have any understanding of this?

Dr. Michael Hynes: I was surprised to learn in the documents from the information sessions that there were lots of laboratories in the country that are not compliant, or we don't know if they're compliant with the guidelines on biosafety that the university and government researchers have to adhere to if they want to get funding. That is a legitimate concern. It makes sense to have legislation that makes this uniform across the country, whether you are a small industry, a big industry, or doing diagnostics or government research.

There should be rules. There is a potential hazard, certainly of level 3 and level 4, and possibly level 2 organisms. The rules should be the same for everybody. Legislation that addresses that is worthwhile.

● (1705)

Ms. Judy Wasylycia-Leis: Okay.

Albert, did you want to add something?

Dr. Albert Descoteaux: I agree with what Dr. Hynes just said.

Ms. Judy Wasylycia-Leis: All right.

I guess I'm getting a mixed message from you. Would you like to see the whole thing withdrawn and started again or do you want to fix this one up?

Dr. Michael Hynes: We're not legislators. We don't know how much work that entails.

Ms. Judy Wasylycia-Leis: Is it fixable?

Dr. Michael Hynes: I would say it's fixable if you leave out the level 2s. That's the general sentiment I'm hearing.

Ms. Judy Wasylycia-Leis: Okay. That's good advice. We'll leave out the level 2s, and we'll try to get some control over the whole process of regulations.

With some other legislation, we have required the regulations to come back to committee for some oversight and to go to Parliament before they're finally approved. To your mind, would that be a useful check in terms of the whole regulatory process?

Dr. Alicia Sarabia: We tried that, particularly about the technology. We're still waiting.

The Chair: Madam Wasylycia-Leis, you have 10 seconds, so there's not much time. Do you want to quickly make a comment?

Ms. Judy Wasylycia-Leis: Alicia did.

The Chair: Dr. Sarabia.

Dr. Alicia Sarabia: I think that would be one option. Another would be to leave in the level 2s but to make lots of amendments just so that it's comprehensive and you're not artificially leaving something out of it that applies to the majority of labs in the country.

The Chair: Thank you so very much.

We'll now go to Mr. Uppal. You had some questions.

Mr. Tim Uppal (Edmonton—Sherwood Park, CPC): Thank you, Madam Chair, and thank you all for coming and adding your professional opinion to this bill.

I'm pleased that we're headed in the right direction. That's important, and I don't think we should be waiting for something huge to happen before we start looking at a bill. So we're headed in the right direction, and we'll try to work this one out.

There's been quite a bit of discussion about level 2s. Just to get it right, in your professional opinion, is it at all possible that in a level 2 lab you can change to level 3 or 4? Dr. Singer was here, and I don't know if he said it or someone else said that there is a possibility that with level 2s, in a level 2 lab it's possible to do that. There's a possibility of making that happen. Is that possible?

Dr. Albert Descoteaux: Do you mean changing a lab that's actually level 2?

Mr. Tim Uppal: Not the lab, but the level 2 pathogen. When Dr. Singer was here he said it was possible to transform a level 2 pathogen to a level 3 or 4. Is that at all possible?

Dr. Michael Hynes: Do you mean with genetic engineering? If you were to clone in a gene from a level 3 or 4 pathogen, by definition your level 2 would be upgraded to the next highest level.

Mr. Tim Uppal: So there's no way to do it just from a level 2 itself?

Dr. Don Low: You can't do it without adding DNA. I just can't imagine such a situation other than in a research laboratory. That would not apply to 99.9% of laboratories that this would impact.

Dr. Albert Descoteaux: In fact, what happens most of the time when you take a micro-organism out of its natural environment, like a human or an animal, where it is infectious, and you passage it in vitro, it loses its ability to cause infection.

In fact, what you would see more often is the other way. You have a virulent micro-organism that becomes avirulent by being passaged in a lab, and that's what happens most of the time. Most of us work with strains that have lost their virulence because of being passaged in vitro. Many vaccines are based on micro-organisms that were passaged many times in vitro so they have lost that virulence, and they can be used as a vaccine. You inject them, and they don't cause any harm except that you get protection from a subsequent challenge by an infectious form of the pathogen. Unless you create a Frankenstein, a monster, there's no way you can have a level 2 pathogen becoming a level 3 pathogen. The other way around is much more likely.

● (1710)

Mr. Tim Uppal: My question is whether that Frankenstein monster is even possible—because we're dealing with biosecurity and safety.

Dr. Don Low: You'd have to know how you would define a level 3 pathogen. What's the definition? A level 2 pathogen in the wrong host is going to cause a disease more severe than a level 3 pathogen. So somebody who has C. difficile colitis is at much greater risk of dying than somebody who has tuberculosis. It's how you define a level 3 pathogen.

The Chair: Dr. Goel.

Dr. Vivek Goel: I think if I understand what you're getting at, the need to control level 2 is because of concerns around bioterrorism. Again, as I think Dr. Carrie referred to earlier, there was the incident when someone sprinkled E. coli on salads.

For things like E. coli or Listeria, you don't need to go to a laboratory to find them. You can go to a lake, you can go to—

Dr. Don Low: Chicken. You can go to the Dominion and—

Dr. Vivek Goel: You can go to Dominion and buy some hot dogs and you can find those pathogens. I think that was referred to earlier.

If you wanted to create outbreaks out of these level 2s, you wouldn't actually go to the lab to get the pathogens. There are all sorts of—Legionnaires' can be found in all sorts of ponds across this country.

Dr. Don Low: Yes. I think it's important to recognize that these level 2 pathogens can be obviously pathogens. But you have a greater risk of getting an E. coli infection barbecuing chicken at home than a technologist has working in a laboratory. I mean, these are organisms that are in our environment. That's why we isolate them in our laboratories, because they cause disease. But the disease comes from their natural environment.

The Chair: Thank you very much, Dr. Low.

Now we're going to Dr. Carrie.

Mr. Colin Carrie: Thank you very much.

I do want to thank the witnesses for being here.

I would like to make a comment, Madam Chair. I think one of the issues we're having here is the way the panels have been set up. Perhaps it would have been better if we had certain, let's say, witnesses in favour of the legislation versus—

The Chair: Dr. Carrie, maybe what we should do after you've asked your questions is go in camera for a few minutes and just discuss this option. We do have more requests that have come up.

Mr. Colin Carrie: Okay. But I do note some of the things that you're bringing up, like the security issues. I know the intention of this bill is not to have the risk 2 groups go through this major security, but for 3 and 4 there is. So there is a bit of reasonableness here.

You know, you or some of my colleagues mentioned timing. You're correct. As with 9/11, things changed into—because Canada does belong to different international obligations, there is an obligation to improve our biosafety, our biosecurity, and that is the intent of this legislation. Knowing that importers have a certain standard, the idea is to level the playing field across Canada.

So I believe we're onside with the intent of it, but there are some significant questions on implementation.

You did mention the consultation processes. I would like to go over that because I do believe, from my information anyway, there was.... The consultation started back in November 2005 with the provinces and territories. That was my understanding.

Again in September-October 2007, the Council of Chief Medical Officers of Health was introduced to the essential elements of the federal framework, and they were invited for their comments.

The Pan-Canadian Public Health Network council was introduced to the essential elements of the proposed framework in November 2005.

Federal laboratories, in November 2006: 87 federal labs were notified that this was going to be happening.

External stakeholders, in September 2007, including representatives of academia, the private sector, distributors of pharmaceuticals, and again some provinces and territorial labs, were introduced to the essential elements of the proposed framework.

Then when Bill C-54 came, there was time for people to react and get some input in through here.

Respectfully, you do have certain legitimate issues that need to be responded to, and I think it would be good if we had a little bit more balance there.

I wanted to highlight a couple of things.

Number one, the fact that the collection, the use, and disclosure of information provisions in Bill C-11, because you did talk about personal information—

● (1715)

The Chair: Dr. Carrie, did you have a question that you wanted to ask as well?

Mr. Colin Carrie: I did want to get a couple of things on the record because I know that—

Hon. Carolyn Bennett: A point of order, Madam Chair.

I think what Dr. Carrie is doing, getting this stuff on the record, is interesting. I think the point that Dr. Goel made is the most important one. There is a very different approach to consultation and information. A consultation is supposed to be two-way, and then you're supposed to have some assured listening, that you were actually heard. Somebody has to come back and say we couldn't do that because of this, or you get to see it reflected in the new bill.

What we're hearing from the witnesses is that they were given information sessions. They expressed their concerns at that, and their concerns have not been reflected in this bill.

So I am suggesting that the department—now they may want to come back on Thursday, in terms of Dr. Butler-Jones, and we may have to figure out a different way of doing this, but I seriously think —

Mr. Colin Carrie: A point of order that is not; that is debate.

The Chair: I'm going to call this to order right now, because we are way over time and the bells are ringing.

If you'll forgive me, Dr. Carrie and Dr. Bennett, I'll make this suggestion. Obviously we are not doing clause-by-clause tomorrow, but we need to have a very brief meeting with the committee. Our time has run out. The bells are ringing. We have to go to vote very shortly.

I need two minutes with the committee. I ask the committee to remain seated for just a minute, because we have to get to the House for votes.

I want to thank you so much. Your comments were very, very good. I'm not being rude, but we have to get to vote, so would you mind departing so we can go in camera for just a minute? We appreciate your coming.

I do think our schedule has changed for Thursday.

I ask any extra people who are in the room if you could just give us five minutes to discuss as a committee.

[*Proceedings continue in camera*]

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