House of Commons
CANADA

Standing Committee on Health

HESA • NUMBER 057 • 1st SESSION • 38th PARLIAMENT

EVIDENCE

Thursday, November 24, 2005

Chair

Ms. Bonnie Brown

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● (0910)

[*English*]

The Chair (Ms. Bonnie Brown (Oakville, Lib.)): Good morning, ladies and gentlemen. It's my pleasure to welcome you all to the 57th meeting of the Standing Committee on Health.

This morning we have a very special guest, Dr. Joel Lexchin, who has written frequently in the paper on a variety of subjects, always with the most progressive attitude possible. He is going to talk to us a little bit about a study we're never going to get to—unless we all come back—and that is the study on prescription drugs. Dr. Lexchin participated in the first round of our study, but that was a very long time ago, and I think we're very lucky to have him with us this morning.

But first, I've been asked by two members of the committee if we could do the motions before he begins, so Dr. Lexchin, if you would forgive us.... Oh, we don't have a quorum for voting. We can't do it. If we get a few more people, then I will stop the meeting at that time, but in the meantime I think we should go forward with Dr. Lexchin.

[*Translation*]

Mr. Réal Ménard (Hochelaga, BQ): My colleague, Mr. Sauvageau, is coming.

[*English*]

The Chair: Are you sure he's walking here now?

I've changed my mind, Dr. Lexchin; we're going to start with you. Could you begin, please?

Dr. Joel Lexchin (Associate Professor, York University School of Health Policy and Management, Medical Reform Group): Thank you very much for the opportunity to be here. I guess you would have been lonely if I hadn't shown up.

I'm here today representing the Medical Reform Group, which is a group of about 300 doctors and medical students. It was formed back in 1979. The Medical Reform Group represents the views of its members on health and health matters through research, public statements, and consultation with other groups who share our aim of maintaining a high-quality publicly funded universal health care system.

The Chair: Excuse me, Dr. Lexchin. We now have the extra body we need to do these motions, so we'll pause for a minute.

The first motion is by Mr. Gagnon. You have it in front of you. It's asking again for a copy of this study.

Are you moving that for him?

[*Translation*]

Mr. Réal Ménard: Yes.

[*English*]

The Chair: Mr. Ménard is moving it. Is there any discussion?

Mr. Thibault.

Hon. Robert Thibault (West Nova, Lib.): Again, I'm supportive of the motion.

[*Translation*]

We support the motion. The department is preparing excerpts to be presented in camera at the committee.

Mr. Réal Ménard: So we can vote on the motion.

[*English*]

The Chair: Thank you.

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

The Chair: Thank you very much.

Motion two by Mr. Ménard is pretty self-explanatory. I think the motivation for it came out of our last meeting.

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

The Chair: Thank you very much.

[*Translation*]

Mr. Marcel Gagnon (Saint-Maurice—Champlain, BQ): Thank you, dear colleagues.

[*English*]

The Chair: Thank you very much.

We also have one of our regular members with us, Ms. Dhalla, and that's good.

Dr. Lexchin, go ahead.

Dr. Joel Lexchin: Thank you.

The Medical Reform Group believes that health is political and social as well as medical in nature, and that health care is a right. We've appeared before a variety of committees over twenty years, going back to the Eastman commission, to discuss prescription drug issues.

We think the question of prescription drugs is extremely important, for a number of reasons. Modern medications have the potential to greatly improve the lives of Canadians, but that potential can only be realized if drugs are affordable, their effectiveness and safety are well understood, they are promoted in a responsible manner, and they are prescribed appropriately. We think there are serious problems in all of these areas, and today we're going to talk about five different issues: changes in the orientation of the therapeutic products directorate, faster drug approvals, drug safety, transparency in the regulatory process, and recommendations for enhancing public involvement in drug regulation.

There are two competing visions of what the prime function of a drug regulatory authority should be. The one put forward by the pharmaceutical industry holds that the main function is to facilitate industry's efforts to develop new products and to approve them as quickly as possible. In this view, medications are commodities and the regulatory authority exists to provide a service to the industry. The second view, espoused by consumer groups and public health activists, sees the primary purpose as appropriately evaluating products to ensure a high standard of effectiveness and safety. Here, medications are seen as an essential element of the health care system, and the regulatory authority exists to provide a service to the public.

Now, these are not black and white; they're shades. We're not saying the pharmaceutical industry is just out to make money, nor are we saying the public health groups don't recognize the issue around the economic viability of an industry. But we do think these two points of view basically represent what the two different groups think.

The recent history of the therapeutic products directorate makes us concerned that it is tilted towards the industry view of drug regulation, especially since the introduction of user fees. This has resulted in drug companies paying about 50% of the costs of operating the agency. With this change in who funds the agency, the TPD appears to be abandoning the precautionary principle, which says if there are grounds for concern around safety, you should wait to put products onto the market. We think it's moving more towards a risk management point of view, which says that unless something has been shown to be unsafe, you can market it and then wait to see what happens before you take any action.

Since the move to cost recovery, approval times have dropped quite significantly. When you get the copy of the brief we've presented, you'll be able to see this in a chart. Essentially, when cost recovery started in about 1994, approval times dropped by about 50%. Since there are relatively few important new drugs introduced into the market in any given year—and this comes from numbers provided through the Patented Medicine Prices Review Board—faster approval times are primarily something that benefits industry.

● (0915)

We also think this push for fast approval times may take on even greater importance with the passage of Bill C-212. Under this bill, if services are not adequate—in other words, Canadian times are not competitive with those of our major trading partners—government departments may forfeit part of the user fees they collect, and in order to avoid these financial penalties, Health Canada may direct even more resources towards making sure the drugs get approved quickly, taking those resources away from things like post-marketing surveillance.

Finally, with respect to timeliness, the TPD has instituted a policy called the “notice of compliance with conditions”, which allows some drugs for diseases such as cancer or HIV/AIDS onto the market before all the necessary clinical testing has been done. This isn't necessarily a bad thing, but it doesn't look as though the TPD then follows up to make sure the studies that are required have actually been done. There are products that have been on the market under this notice of compliance with conditions for over six years without the necessary clinical studies having been done; at least there's no public record of their having been done.

Comparatively little attention is paid to monitoring the safety of drugs already on the market. In the throne speech of 2003 the government promised an additional $190 million into the regulatory system over a five-year period. In 2003-04, $40 million of that was allocated, with over $31 million going to make sure the drugs got onto the market faster and $2.5 million going to monitor the safety of the products that are already on the market.

We think this kind of relative allocation of money is grossly inadequate. The health products directorate has stopped trying to routinely assign causality when it gets reports of potential adverse drug reactions, because it doesn't have the money to do it. Safety alerts that are issued around drugs don't appear to be having any effect on the prescribing and use of those medications. For instance, in the late 1990s there were safety alerts issued around cisapride, without any effect on prescribing behaviour. There were safety alerts issued around one of the statins for lowering cholesterol without any appreciable change in prescribing. In fact, prescribing actually went up after those safety alerts were issued. Both of these products then had to be withdrawn from the market because of safety concerns.

There's evidence from both the United States and the United Kingdom that faster approvals lead to greater safety concerns around drugs; however, at this point Health Canada puts so little emphasis on safety issues that it couldn't even produce a list of drugs withdrawn from the market for safety reasons when I asked for that kind of list about a year and a half ago. They had no way of tracking which drugs had been removed for safety reasons. I ended up producing such a list.

● (0920)

It turns out that although, in the seventies and eighties, we were withdrawing about seven drugs a decade from the market for safety reasons, that number has doubled effectively in the 1990s and early 2000s. But there is no way of analyzing why that number has doubled, because Health Canada doesn't even track the drugs it has withdrawn for safety reasons. So if you don't know the ones you've taken off, there's no way of analyzing why the number has been increasing.

Drug regulation in Canada is shrouded in secrecy. Even the names of drugs that are in the approval process are not publicly disclosed, and all the information that industry submits, including clinical trial data on safety and efficacy, is deemed confidential. You can only get that if you file an access to information request, and then only if the company agrees. Based on the access to information requests that I've filed over the years, the information you get back has all the important data whited out, so there's no way of being able to analyze these studies.

The level of secrecy not only harms, potentially, consumers and health professionals, but it can even have negative effects on the TPD, because there's no way for outside experts to review what the TPD reviewers have done and provide them with feedback. So this means, effectively, that they're operating outside of the rest of the scientific community. That's contrary to general scientific practice. Peer review is one of the cornerstones of modern science. You publish your findings, and other people look at them and provide critiques of them so that you can do a better job next time. People can learn from mistakes. But with the level of secrecy we now have, that's impossible.

In response to criticisms about secrecy, the TPD recently announced a new initiative called the summary basis of decision. In our view, the key information that will be in this new document is information about drug effectiveness and safety.

In recent years, access to information that regulatory authorities have about drugs in the U.S. and some European countries has allowed independent researchers to discover problems with drugs that were not identified in the review process. So we have taken these drugs, and then the pilots of the summary basis of decision documents, and looked to see whether or not the information in the SBD would have been sufficient to uncover these safety and effectiveness concerns, and it would not have been. The SBD lacks key information that would allow people to identify new safety and effectiveness concerns.

We have four recommendations for enhancing public involvement in the regulatory system.

First, a detailed summary of all clinical information that companies submit as part of the regulatory process should be routinely posted on the TPD website, and in addition, the reports of the TPD reviewers should be posted on the website.

● (0925)

We think applications for approvals of new drugs should go to expert advisory committees. These are committees made up of outside experts.

Hearings of these committees should be public, as they are in the United States. The information the committee members get before the meeting should also be public, as it is in the United States, and interested members of the public should be able to make presentations to the committee.

These committees should also be governed by strict conflict of interest standards, so we don't have a situation such as the one we recently had with the breast implant issue, where a number of the people on the advisory committee had appeared for the manufacturers or had done research in favour of the manufacturers.

Finally, we think that if drugs are refused approval, either new drugs or new indications for old drugs, that information also needs to be made public. For new drugs the manufacturers may come back with another application in the next year or two. We think the public has a right to know why the drugs were refused in the first place and if those deficiencies have been corrected. For old drugs, if there are applications for new uses that are turned down, that's also important, because there's no way of regulating what doctors are actually prescribing drugs for and what members of the public are taking drugs for. So the application for a new indication may have been turned down, but doctors may go on prescribing for that indication without ever being aware of the fact that the regulatory authority did not think that the evidence was adequate to allow approval for that.

That's a brief summary of our brief. I'll be happy to answer any questions anybody has.

● (0930)

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

We'll begin the questions and answers with Mr. Merrifield.

Mr. Rob Merrifield (Yellowhead, CPC): I'll be splitting my time with Mr. Fletcher.

The Chair: Okay, five and five.

Mr. Rob Merrifield: Okay, that'll be fine.

I have just a few questions. I think what you're saying, and I'm just summarizing it quickly, is that you don't have a problem with pharmaceuticals. We use pharmaceuticals. There's benefit to pharmaceuticals. But you're suggesting that the transparency in their approval is not up to speed, and you have some significant concerns about that process.

Is that where we're at?

Dr. Joel Lexchin: Yes, the people in the Medical Reform Group are doctors. I work in an emergency department. When I'm there, I write prescriptions on a daily basis. I've used medications myself, and we certainly recognize that medications are a cornerstone of the health system. We're not against medications. We're not against the companies that make them.

What we're in favour of is being sure those medications are used appropriately, that we're not rushing things through the system to satisfy the financial interests of the pharmaceutical companies, and that we're adequately monitoring the safety of products that are already on the market so that they continue to be used appropriately.

Mr. Rob Merrifield: Yes, that's what we found. Your comments are in line with what we found last time we took this study. We were rushed—actually, it was prior to an election, I believe—in issuing a report, though not quite as rushed as I believe we will be this time. Nonetheless, it was inconclusive, and that's why we're picking it up again.

We were alarmed at some of the things we were finding on that side of it, particularly with post-market surveillance, the lack of adverse event reporting, and then how it could be solved. We never really got into that. We pointed to the problem, but we didn't point to any solutions, so hopefully we'll pick that up now and start looking at some of the solutions.

Just to get what you're saying straight, I think you're saying that we reduced our timing for approval rates by 50% in the nineties.

● (0935)

Dr. Joel Lexchin: Yes, we did that in the late nineties, the mid- to late nineties.

Mr. Rob Merrifield: But even now, are we not significantly slower on the approval times than, say, the United States and other industrialized countries?

Dr. Joel Lexchin: We're slower on approval rates and for the few drugs that represent major advances. If you look at information from the PMPRB, that is roughly between 5% and 10% of the drugs that come on the market in any given year. They classify them as breakthroughs, in other words, first products to treat a problem, or major therapeutic advances. So in those instances, you can certainly make a good case for faster drug approvals. But for the rest of them, since they're not going to make much of a difference, I don't see any reason why we should be rushing those through the approval system.

Mr. Rob Merrifield: If it looks like a blockbuster drug, something really significant, we can accelerate that. Is that what you're suggesting?

Dr. Joel Lexchin: Accelerate it, but also, if we're going to accelerate it, which is what we do under this notice of compliance system, with conditions, we actually have to make sure those conditions are being fulfilled. Doctors need to know what the conditions are. If you look at the drugs that are approved under the notice of compliance with conditions, all you see is that there are conditions. You have no idea what the conditions are.

Mr. Rob Merrifield: That gets to the secrecy around the whole licensing, which is what you've addressed.

Dr. Joel Lexchin: And it also gets to the issue that the TPD, in a number of cases, doesn't seem to be doing anything to make sure those conditions are being fulfilled. As I said, there was one product introduced, I believe in August 1999, that still doesn't have its conditions fulfilled.

Mr. Rob Merrifield: I'm not arguing with anything you're saying, necessarily, but I'm trying to clarify what you're saying. When we get into some of the solutions, though, and the reporting of adverse events, you didn't touch on that.

Dr. Joel Lexchin: That's an appendix to our brief. I can talk about that, if you'd like.

Mr. Rob Merrifield: Well, we recognize it as one of the problems we saw: 1% to 10% are being reported now, so if you're not reporting them, how can you follow them through and really act on any of these outcomes? I'd like to hear your comments on where you think we should go on that, especially as a doctor.

Dr. Joel Lexchin: Okay. There are a number of ways you can deal with this problem.

First of all, you can start by using these conditional approvals. You can either have conditional approvals or you can have mandatory five-year reviews, which will then look at safety issues. So you can either mandate that the drug companies conduct additional trials to address safety issues, because one of the things we know about drugs is that when they're approved, they've been tested in relatively small populations, usually middle-aged people, men and women who have clear-cut diagnoses, who are not taking other medications and who don't have other health conditions.

Mr. Rob Merrifield: But as physicians, wouldn't you be in the ideal position to determine whether you're seeing adverse events or not?

Dr. Joel Lexchin: Not if you're not trained to look for them, which is—

Mr. Rob Merrifield: Maybe there's a fault in the training of physicians, then.

Dr. Joel Lexchin: That's one of the issues. But right now there's no incentive, there's no feedback to doctors to provide.... When you do file a report, you don't know anything about what's going on. So one of the things we think should be happening to encourage doctors to file reports is that when they do file them, they get rapid feedback, not only about the report they filed but also summarizing what other reports have been filed, and that they're kept up to date about what's going on with that product.

● (0940)

Mr. Rob Merrifield: Electronic health records are a vehicle that could be used to do that.

Dr. Joel Lexchin: Electronic health records could be helpful. One of the ways of looking for adverse drug reactions is to use databases and link them. For instance, you could set up, with appropriate privacy concerns, a registry around, say, the first 10,000 people who get a new drug. Then you could follow what happens to them, how many times they visited the doctor in a month, six months, one year after they got the drug, how many times did they go to hospital, what they were in hospital for.That kind of thing would help identify new unexpected and adverse reactions.

The Chair: Mr. Fletcher.

Mr. Steven Fletcher (Charleswood—St. James—Assiniboia, CPC): Thank you, Madam Chair.

As my colleague Mr. Merrifield pointed out, Canada takes probably on average twice as long as the United States in the drug approval process. On one hand, we have to be cognizant of the safety issues, but on the other hand there are people who can benefit from having many of these drugs online sooner. If I recall correctly, orphan drugs are an example of where trials can take a long time. The people who are on the drugs for the period of the trial get a lot of benefit, but when the trial ends, the delay between when they're actually approved can be life-threatening for those people because they can't get access to the drugs that have been prolonging or improving the quality of their life.

I wonder if you have any comment on the balance between the safety on a large scale, which I think is a very important issue, and the other side of it, which is the benefit that people could have if the drug were proven to be effective.

Dr. Joel Lexchin: We think that important new drugs, drugs that provide substantial benefit to people, should definitely be approved as quickly as possible, recognizing safety issues. If there are safety issues that remain unresolved, but there are clear benefits, those safety issues should be studied in mandatory post-marketing trials. We're not against people getting drugs quickly that provide substantial benefit. What we're against is rushing drugs through the marketplace that will not provide any additional benefits.

So for instance, there's a new class of drugs to treat hypertension called the angiotensin receptor antagonists. We now have six of these products on the market, and we see no value in rushing a seventh one through that will be no different from the other six.

Mr. Steven Fletcher: Okay, I'm going to move on because I have limited time.

Presumably, if we got e-pharmacy going throughout the country, and electronic medical data, we could do these post-market evaluations more readily. Would you agree with that?

Dr. Joel Lexchin: That would be one of the ways of enhancing post-marketing surveillance. There are a number of others.

Mr. Steven Fletcher: My last question deals with the drug approval process in the EU. As I understand it, the country that approves a drug for trial first automatically...and I'm simplifying it. It becomes an approved drug throughout the entire EU. Presumably the life of someone in Greece is just as valuable as someone's life in Britain or Spain, so I think the assumption is, provided that they have common standards, whichever country can get the approval first, that's great, and it carries through.

Is there any way Canada can synchronize our approval process with other countries that have similar standards?

● (0945)

Dr. Joel Lexchin: We could certainly use data from those countries, but we also have to recognize that different countries make different decisions around drugs. Even between Canada and the United States, there are drugs we approve that aren't approved in the U.S., and vice versa, there are drugs we turn down that are approved in the United States.

So we need to maintain or own regulatory system. We certainly can share data, but one of the issues that will have to be resolved if you share data is differences in transparency around that information. So if the EU has stricter secrecy rules than Canada and we're getting data from the EU, will that information then be able to become publicly available?

Mr. Steven Fletcher: I guess they've figured it out over there somehow. But that's 17 or 18, or many sovereign nations.

Dr. Joel Lexchin: They keep things secret. Everybody does.

Mr. Steven Fletcher: Yes, okay.

There are issues around data protection, but I don't have time to ask that. I'll have to save that until the next session of Parliament.

The Chair: Thank you, Mr. Fletcher.

Mr. Ménard.

[*Translation*]

Mr. Réal Ménard: I will begin by asking a general question.

When we try to understand what is involved in establishing the cost of drugs and when we read reports on the Internet or from health information institutes or other organizations, such as the Patented Medicine Prices Review Board, we learn that there are three factors. First of all, the most significant factor is the introduction of new drugs. In the first year, prescribers are under a great deal of pressure to use these drugs.

Could you tell us how your institute and you explain the cost of drugs? Do you have any information on the National Prescription Drug Utilization Information System? This system, which was set up at the time of the federal-provincial Health Ministers' Conference in 2001, was to be used to monitor pricing trends of drugs. Have you ever heard of it? How should we, as elected officials, view it?

[*English*]

Dr. Joel Lexchin: The main issue that drives increased spending on drugs in Canada is the switch from older, less expensive products to newer, more expensive ones, which aren't necessarily any better.

You can look at spending by the drug companies in promotion of some of these new drugs, which is one of the main reasons they're taken up so quickly. For instance, for Vioxx, in the year 2000 Merck spent over $6 million promoting that product. They had 48,000 visits by their sales representatives to doctors' offices, and they left behind over one million samples of that product for doctors to use. With Celebrex, there were 77,000 visits by sales representatives in one year for that one product alone. It's this heavy promotion of new drugs that often drives both doctors to prescribe them and patients to ask for them before their full value is understood. That's why, after inflation, drug spending in Canada is going up at the rate of about 7% or 8% a year—three times higher than the CPI.

The system you're talking about that was set up in 2001 is nice in theory but hasn't resulted in very much in practice. That's because we don't have any good mechanism on a national basis that can influence the way doctors prescribe, and the way patients use, medications.

In Australia, for instance, there's something called the National Prescribing Service, which is funded nationally to the tune of about $25 million a year. Its money comes from the government, but it's run independently—something like a crown corporation—and its sole mission is to improve the prescribing and use of all drugs.

● (0950)

[*Translation*]

Mr. Réal Ménard: Should we not be concerned about the fact that the owners of generic drugs are not accountable to anyone?

Personally, I have in the past wanted to table a private member's bill to ensure that generic companies come under the authority of the Patented Medicine Prices Review Board. However, I was told that this would be unconstitutional since the federal government was responsible for the review board given its jurisdiction over patents, and that this could eventually be challenged.

When we did the previous study, we wondered about whether or not the Patented Medicine Prices Review Board could examine what the generic companies are doing.

In your opinion, could we exercise some measure of control? Even if the prices are lower, we still do not know what research is being done: these companies are accountable to no one. Do you think that the Patented Medicine Prices Review Board should play some role in governing the generic companies?

[*English*]

Dr. Joel Lexchin: I'm not a constitutional lawyer, so I don't know how far the authority of the PMPRB could go.

First of all, we should recognize that while generic drugs in Canada may be more expensive than those in other countries, such as the United States, on the whole generic drugs make up only about 13% or 14% of total drug spending. If we lowered generic prices or even cut them in half, we would only be affecting a relatively small percentage of the overall spending on drugs in Canada. However, this is not to say we shouldn't be doing something about them.

The way of controlling generic drug prices may be through the drug plans that the provinces currently have, where the provinces have established various rules around prices for generics that they will let onto their formularies. Unfortunately, those rules don't seem to be terribly effective.

For instance, in Ontario the first generic competitor has to come in at 70% of the brand, and subsequent generics need come in at 90% of the first generic. Instead of being ceilings, those prices have become floors. It may be that if the provinces want to control generic drug prices, they need to get together and have one negotiation instead of ten separate sets of negotiations, and one set of rules, which will effectively lower generic drug prices.

● (0955)

The Chair: You're well over the time. Thank you, Mr. Ménard.

We'll go to Ms. Dhalla, and then Mrs. Crowder.

I'm being very indulgent this morning.

Mr. Réal Ménard: Yes. You know that I love you.

The Chair: I know, and it's worth it.

Ms. Dhalla.

Ms. Ruby Dhalla (Brampton—Springdale, Lib.): Thank you very much.

After all of those words, we want to thank you so much for coming.

I have a couple of questions.

As you're aware, there are a number of different pharmaceutical companies in the industry that try to entice physicians and perhaps provide them with an education in respect to using particular pharmaceutical products. The enticement would involve having seminars over lunch periods and perhaps going away on trips, whether it's down south or to Europe, to learn about the products.

What type of impact do you think that has had on physicians utilizing pharmaceutical products, when these pharmaceutical companies are wining and dining them?

Dr. Joel Lexchin: As an obsessive compulsive, which we have drugs to treat, one of the things I've done is collect the literature that looks at how well doctors prescribe as a function of where they get their information. These studies have been done for more than 30 years now in a variety of countries—not in Canada, but in the United States, in the U.K., in some of the European countries—and all of the studies have uniformly found that the more the doctors rely on information that comes from the pharmaceutical industry, the poorer the job they do in terms of prescribing. So they tend to prescribe more expensive drugs when less expensive ones are available and equally effective. They prescribe the wrong drugs. They prescribe more dangerous drugs when less dangerous ones would be effective. Whatever measure has been used to look at the quality of prescribing, they do a poorer job.

Ms. Ruby Dhalla: There have been some controls put in place—some were put in last year—that provide restrictions on pharmaceutical companies in terms of violation fines. Do you think that has had an impact on pharmaceutical companies, on that relationship they've had with physicians?

Dr. Joel Lexchin: Not particularly. First of all, the government has traditionally refused to directly regulate promotion. They've turned over regulation to either the industry, in the case of the activities of the sales representatives or the conduct of company-financed continuing medical education, or in the case of print advertising, to the Pharmaceutical Advertising Advisory Board. The industry's code is really designed to level the playing field for the companies. If you look at who makes complaints about code violations, it's not doctors or the public, it's one company complaining about another.

The fines that are available are really quite piddly. If you violate the code three times in one year, the current maximum fine is $15,000, which is about the amount of money the drug companies will spend taking one group of doctors out to dinner one time. It's lunch money, supper money. When you park downtown in Ottawa in a no-parking spot, you figure you're going to get a fine, and that's just the cost of driving a car around in a large city.

● (1000)

Ms. Ruby Dhalla: Do you think the federal government, and in particular Health Canada, should play a role in providing some sort of regulation for this type of advertising?

Dr. Joel Lexchin: I think that promotion needs to come under the government regulation, but it should not be done by Health Canada. If you look at what goes on, for instance, in the United States, with the Food and Drug Administration there, the degree to which they control promotion is heavily dependent on which party is in power and on how friendly or unfriendly it is towards the pharmaceutical industry.

I think what we need is a separate organization that has its basis in legislation so it has the legislative authority to regulate, but that is independent of government. So it would be something like a CRTC. The members would be appointed by government, but then this organization would operate independently of government and would do the regulation of all forms of promotion and have the ability to level sanctions that are meaningful to the companies.

Ms. Ruby Dhalla: Thank you.

There's no doubt about it, the pharmaceutical companies do provide a tremendous number of jobs in the country and spend a lot of money in research and development. But I think there needs to be some sort of balance so when physicians are prescribing, the patient's interest is first and foremost.

My last question, just before I pass the floor on to my colleague, is in regard to data protection. It's an issue that has come up amongst both the generics and the brand names as well. Canada, as you know, at the moment does not have any type of data protection available. In terms of ensuring global competitiveness for many of these pharmaceutical companies, especially on the brand side, they require that. There was a proposal put forward to look at between five and eight years.

Could you comment and let us know what your thoughts are on that?

Dr. Joel Lexchin: Data protection has the potential to delay the appearance of generic drugs on the market. Even though our generics may be priced higher than ones in the U.S., they still represent substantial savings in costs.

Generic companies are not going to undertake the kinds of trials that are necessary to reproduce the information that would be protected under data protection. It would not really be ethical for them to do so since they would subject patients to risks that are already known just for the purpose of generating information.

This is an instance where we need to balance what we think are the economic benefits of more industry investment—and that's speculative as we don't really know what the industry will do in terms of investing in Canada—versus getting generic drugs on the market faster and saving money in the drug bill.

The record of the brand name companies on investing in Canada is mixed. Some companies do a much better job than others, but on the whole, Canada is one small part of a very large world market. We represent under 2% of the world market. I think that to expect substantial investment from drug companies in Canada may be unrealistic.

● (1005)

The Chair: Automotive companies make major investments in Canada even though the market is equally small within the frame of the world market, so I don't understand why big pharmaceutical companies wouldn't want to invest in Canada to do some of their peer research. It seems to me that a lot of them keep all those...what I call high-paying jobs, research jobs, in the country of their birth—the birth of the company, that is.

Dr. Joel Lexchin: That's certainly true. The only country that gets substantial research and development investment from companies that don't have it as their home base is the United States. There are probably a number of reasons for that, and one is the size of the market. The United States represents 50%, roughly, of the world pharmaceutical market.

Secondly, the heavy investment by the National Institutes of Health in basic research is something that draws companies into the United States. The NIH spending is currently about $27 billion a year; that compares to the Canadian Institutes of Health Research at about $700 million per year.

If we were to invest public funds in medical R and D to the same extent on a per capita basis as the United States does, we should be spending almost four times what we are. That might be something that would attract the companies into Canada. If we were generating a substantial amount of basic scientific information, the companies would use it to develop the products. They tend not to do that basic research, but they're very good at taking that basic research and then applying it and developing new products.

The Chair: Thank you.

Mrs. Crowder.

Ms. Jean Crowder (Nanaimo—Cowichan, NDP): Thank you

I want to thank you for your presentation today.

I want to start with a comment. We often talk about investment in the country, in this case by pharmaceutical companies, but what I don't hear us factoring into that is the cost of what happens with inappropriate prescribing or dangerous drugs. That doesn't ever seem to get offset. It's just a comment.

You raised the issue of silicone gel breast implants as an example of things around conflict of interest. I've got a couple of questions for you, and I'm going to use this. Although it's not a drug, I think it's an example of how the process in Health Canada does not work for the consumers.

You specifically mentioned the conflict of interest standards, and there are two things I'd like you to address.

One of the arguments we heard from Health Canada around conflict of interest standards around the silicone gel breast implants is that it was very difficult to get expert advice unless they went to people who had worked in the industry. I'd like you to specifically comment on whether or not we could find other expert advice that wouldn't be industry driven.

The second piece is around the public process. You said you thought the hearings should be public, but I wonder if you could elaborate more on what an adequate public process would look like. Certainly in the case of silicone gel breast implants it was heavily weighted towards industry; other public input was minimized and difficult.

I wonder if you could speak to conflict of interest and public input.

● (1010)

Dr. Joel Lexchin: First, in terms of whether or not you can get experts who have not been involved with industry, one of the issues here is the difference between clinical experts, in other words people who have actually been involved with the trials, and people who are, for a lack of a better word, evidence-based medicine experts. These are people who have been trained to be able to look at studies from a wide variety of medical products, look at the quality of that information, and decide whether or not that information justifies marketing products and how safe they are.

It is true that if you're looking for clinical experts, a lot of them are likely to have been involved with the drug companies. But if you concentrate on finding evidence-based medicine experts, you'll probably be able to find independent people who will be able to evaluate that information. For instance, when they set up the review committee to look at Adderall, a product that was temporarily removed from the market that was used to treat children with attention deficit hyperactivity disorder, the person who headed that three-member committee was an evidence-based medicine expert who had not had involvement with the companies making that kind of product. The experts who have been involved with industry should certainly be allowed to testify before these advisory committees, but that's no reason why they should be members of those committees.

In terms of what an adequate public involvement system would look like, the first thing we need to do is recognize the significant difference in resources. A lot of the groups that would like to attend these things and make comments are groups with very limited resources, certainly compared to the resources that would be available from industry or groups that have their funding from industry. There has to be provision around public money and public resources that can be given to groups that are independent of industry but need the resources.

Second, there has to be an adequate amount of time for these groups to look at the information that is available in order to be able to make their comments, which means that information that's going to advisory committees should be available at least a few weeks, if not longer, before those committees meet so people can have that information available. We need to be sure that the committee hearings are held at times when people are available to be able to travel. Having single days or two days of committee hearings may not be adequate, given the size of this country and, as we've seen today, the weather, to allow everybody who wants to attend to be able to do that. One of the ways we might be able to get around that is by using video conferencing to allow people from Vancouver, for instance, to participate in committee hearings through the use of video conferencing.

● (1015)

Those are just a few of the possibilities around allowing for adequate public involvement.

Ms. Jean Crowder: Concerning the issue of secrecy, as we discovered with silicone gel breast implants not only could witnesses not get access to information, but the committee itself couldn't get access to information. We couldn't access the information from the March scientific panel hearings. We were told there were no minutes. Now it seem it's questionable whether we'll have access to the chair's notes. And we still haven't been able to access that cohort study from 1996.

So when you talk about people who want to appear before a committee having information available to them, it would require a huge shift in the way Health Canada operates.

Dr. Joel Lexchin: It would, although even under the current Access to Information Act there actually is a provision that allows Health Canada to release information if it's in the interests of public health. They have never acted on that provision in the act. The one time somebody went to court to try to use it, they lost because the wording says something like “the minister may release” or “should release”; it doesn't say “the minister must release” if it's in the interests of public health.

The Chair: Do you remember who the minister was at the time it failed?

Dr. Joel Lexchin: This was in the mid-to-late 1990s. I can't remember—David Dingwall, perhaps?

The Chair: No, he was very early.

Dr. Joel Lexchin: Okay. I don't remember who the minister was at the time. But this was a case that dragged through the courts for a few years.

The Chair: Did you have any more?

Ms. Jean Crowder: I just have one more quick question. You're probably familiar with a recent book that came out called *Selling Sickness* by Moynihan and Cassels, and you've talked about the impact on prescribing behaviour when pharmaceutical companies interact very vigorously with physicians.

I don't have the numbers, but my understanding is that there was supposed to be a certain amount of research and development happening in relationship to the advertising that happened. I don't remember what the ratio was, but I know it's not happening, from the recent report that came out.

Can you comment on that?

Dr. Joel Lexchin: I think what you're referring to was the verbal commitment the industry made back in the late 1980s when Bill C-22 was going through Parliament. They said they would invest 10% of sales in research and development. Up until about 1996, they were doing that. In the past three or four years, the level of investment has dropped below 10%.

If you compare the amount spent on research and development in Canada with the amount spent on promotion, roughly twice as much money is being spent on promotion as on research and development. The estimate I have of promotion spending is about $2.2 billion a year, versus, I believe, $1.2 billion on R and D.

● (1020)

Ms. Jean Crowder: Thank you.

The Chair: Thanks, Mrs. Crowder.

Mr. Gagnon.

[*Translation*]

Mr. Marcel Gagnon: Thank you, Madam Chair. First of all, I would like to apologize for being late. This morning's storm took us all by surprise. I spent part of my morning waiting on the bridges.

I would have liked to have participated more in this discussion, but you did hit on a point that surprised me when you said that twice as much money was spent on advertising as is spent on research and development. I'm surprised, particularly at a time when we are worried about a pandemic arriving, for example, and when AIDS is still in the news, that we spend so little money on research and development.

Am I mistaken? Do you feel that we spend little money on research and development? Is it enough?

[*English*]

Dr. Joel Lexchin: As I said in response to another question, companies tend to concentrate their R and D spending in the country where their head offices are, which means that the countries with the most amount of money being spent on R and D are the United States, the United Kingdom, France, Germany, Japan, and Switzerland. Those are the countries where about 90% of the large pharmaceutical companies are located, and those are the countries that get the R and D spending.

It would certainly be helpful for Canadian scientists to be able to access more funding for medical research. There are, however, a couple of issues we need to think about when we're looking to generate more drug company-funded R and D. The first and main issue is where that investment is going to go and what kind of research will be done, and while research into drug products is certainly desirable, that's the only place by and large that the drug companies will make their investments. This will mean that a number of areas around health care would not receive funding.

As an example, in the case of sexually transmitted diseases among teenagers, if you wanted to look at the use of an antibiotic to treat them, you would probably have no trouble getting money from a drug company. But if you wanted to look at changing the sexual behaviour of teenagers so that they didn't transmit the diseases in the first place, there is no commercial product available to come out of that research, and so drug company money would not be likely to go there.

Yes, it would be nice to get more drug company money, but we have to recognize that the research will follow the money, and if we don't have adequate public funding for research, then important questions will never be asked, because there's no money to answer them.

The Chair: Do you have another question?

[*Translation*]

Mr. Marcel Gagnon: No, thank you.

[*English*]

The Chair: I want to ask you a question, Dr. Lexchin.

As I said first of all, we're hopeful that all our members at the health committee will be re-elected, and we're hopeful they'll all come back to this committee so that we can go forward with this particular study. As Mrs. Crowder has pointed out, if we could get the drug approval process correct and the post-market surveillance correct, and get certain parameters around the activities of the pharmaceutical companies—we have big ambitions on this committee, as you can see—it would be tremendously meaningful, I think, for the health of Canadians.

While you're here, it seems to me we may probably be in need of someone who, I would suggest, is a legal expert on data protection, patents, etc., but has an interest in health. I'm wondering whether your group has ever either run into or hired such a person to advise you, because in so many alleys we want to walk down and shine a flashlight into, we find there's a door we can't go through because of patented information that isn't available to us.

● (1025)

Dr. Joel Lexchin: The Medical Reform Group, despite being made up of doctors, is relatively poor, so we have never hired or sought legal expertise. However, there are a variety of organizations that do either employ lawyers or have lawyers as their members who do specialize in these areas.

The Chair: Could you give us some names.

Dr. Joel Lexchin: Médecins Sans Frontières has lawyers who work for it. They're trying to use the Jean Chrétien Pledge to Africa Act to get drugs that could be exported to third world countries. There's also an organization called the HIV/AIDS Legal Network, which is a lawyer-based organization. While they do deal just with drugs for HIV and AIDS, their expertise does extend to general patent issues.

The Chair: We as a group don't have a lot of money either, but we luckily can ask the highest-priced lawyer in town to come and help us. They usually come out of their civic duty, which is great. That's why we like to get suggestions from people like you. That's why we have you. The biggest experts in the country are available to us and we're very grateful. We're very grateful to you for coming today.

Did you come last night?

Dr. Joel Lexchin: I came before the snow, yes.

The Chair: Lucky you. Now you have to get home, which could be a problem.

In any case, I thank you very much, and I hope this meeting will be the motivation for the next committee, whoever is on it, to pick up the thread and march forward.

Thank you very much.

Dr. Joel Lexchin: Thanks very much for agreeing to hear me.

The Chair: My pleasure.

This meeting is adjourned.

Published under the authority of the Speaker of the House of Commons

Publié en conformité de l'autorité du Président de la Chambre des communes

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