



CBC Radio's As it Happens
EASY DRUGS

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Interview with Health Minister Tony Clement and Canadian Health Coalition's Michael McBane

DESCRIPTION: "Protecting Canadians" was the stated goal said the Prime Minister in a grand announcement earlier this week in Ottawa. The government has introduced long-promised legislation to ensure consumer safety in everything from food to toys to drugs. To that end, the Health Minister also announced the first update to the country's Food and Drugs Act in 50 years. One of the key revisions, according to media reports, will allow new drugs to get to market faster. And critics fear that change may not protect Canadians at all.

Transcript Begins:

BARBARA BUDD (Host): Protecting Canadians – that's the stated goal in a grand announcement by the Prime Minister earlier this week in Ottawa. The government has introduced long promised legislation to ensure consumer safety in everything from food, to toys, to drugs, and to that end the Health Minister also announced the first update to the country's Food and Drugs Act – first update in fifty years. One of the key revisions according to media reports will allow new prescription drugs to get to market faster and critics fear that change may not protect Canadians at all.

Tony Clement is the federal Minister of Health. He's in Ottawa.

CAROL OFF (Host): Mr. Clement we want... we know that a lot came out in this consumer announcement, but we want to focus in on the decision to fast-track the new... the drug approvals. Tell us, if these changes are about protecting Canadians, how does that protect Canadians?

TONY CLEMENT (Minister of Health): Well I don't think that would, which is why we're not doing it. We're not fast-tracking. We never were fast-tracking. We've got the same licensing procedure in place for drug approvals as has been in place at the initiation of the licensing. What we're doing though of course is extending our reach and our

regulatory authority to the whole life cycle of the drugs so that we can continue to monitor, continue to do science on these drugs, and if there are problems with adverse reactions we'll have the ability to react to that a lot quicker.

OFF: But you're endeavoring to bring these new drugs to market faster?

CLEMENT: No.

OFF: Well then explain what you are doing with the drugs then.

CLEMENT: Well what we're doing is we're continuing to ensure that we have the same stringent licensing procedures for drugs at the initial stage of licensing, but we're extending our review and our monitoring of the drugs throughout the whole life cycle of the drug - life cycle meaning however long the drug is on the market. And so we will be in a position to monitor, a position to consider science, a position to react to any new science that is out there or adverse reactions that come to our attention. And what we're doing is having a mandatory system of adverse reaction monitoring in all of our hospitals across the country so that if a person gets sick, gets hospitalized as a result of a drug we will have an ability to know that information and that will of course be very germane to whether that drug remains on the market or not.

OFF: The monitoring of the safety for drugs already on the market is usually follows the FDA, the US Food and Drug Administration, in any investigations or warnings or recalls. How will this legislation help Health Canada better monitor safety and to act first instead of after the FDA? Or will it?

CLEMENT: Well I think that basically what happens in the world today is a lot of this is based on the best science and sometimes the best scientists are in Canada, sometimes the best scientists might be in another country, and so we pool that information. We let the science do the dictation as to whether a product is safe and healthy to use. But of course we want industry to prove to us that it's safe for Canadians to consume as well.

OFF: And will you endeavor to get the drugs to people faster?

CLEMENT: No, I will endeavor to get the drugs to people safer, and if it takes longer to get that drug to market than people would like I understand and certainly that's regrettable, but the fact of the matter is we have to make sure that a product is absolutely safe for consumption. So that's my number one priority is health and safety.

OFF: Is it your sense that these reports as everybody is reporting in the papers today that what you have done is to fast-track this, so are you saying these reports are wrong?

CLEMENT: Well I would encourage media to read the legislation because they are spot wrong on that.

OFF: On the enforcement side, the new legislation will increase fines for drug companies that manufacture or distribute unsafe drugs. Those fines will go from five thousand to five million dollars. Is that correct?

CLEMENT: That is correct.

OFF: How often in the past though have drug companies even been fined the five thousand dollars?

CLEMENT: Yeah, I'm sure it's fairly rare. What I would say is what we've done is we've done a couple of things. First of all we've increased the maximum fines. The second thing we've done is we've added a whole layer of potential fines called administrative fines. So these ones would be able to be administered by inspectors on the spot, and so that way we can... we can enforce our rules a lot quicker, the paying for the manufacturer or for the retailer is a lot quicker, and of course at the back end if the conduct is particularly egregious then we have these maximum fines which of course are going to be higher than the United States, higher than most other parts of the world as well. So I think actually we've not only brought Canada within the twenty-first century from the twentieth century when it comes to consumer safety, we're actually now going to be leading the pack and that that's the reaction we're getting from Safe Kids Canada and other stakeholders.

OFF: You've made the point that this is the first time in fifty years that the Food and Drug Act has been reviewed and revamped. Does it go far enough or are you planning more?

CLEMENT: Well listen, you know I think we've gone a great distance and of course this bill has not been passed by Parliament so there may be some good ideas that come up as Parliament debates this bill. So I don't want to close the door to some new good ideas, but I would tell you we had a lot of consultation with consumer advocate groups, consumer safety groups. They are very happy with this legislation. It finally, I believe, puts the correct onus on industry to produce safe products. It gives consumers more information so they can make better choices, and at the back end government is there to ensure that if there is a problem we have the powers to recall and the powers to fine.

OFF: Given the paralysis that we're seeing in committees in Parliament, how likely is it that you'll get this passed?

CLEMENT: Well you know the Health committees work pretty well the last couple of years, so I'm optimistic that we'll have obviously a full and robust debate as parliamentarians do and should have, but at the end of the day we're trying to protect the health and safety of Canadians and I'm hoping the Opposition parties will view it in that regard.

OFF: Mr. Clement, thanks for speaking with us.

CLEMENT: Thanks very much.

OFF: Bye-bye.

CLEMENT: Bye-bye.

BUDD: Tony Clement is Canada's Minister of Health and we reached him in Ottawa.

Well you know we got a little confused by the Minister's insistence that his government is not moving to get drugs to market more quickly. We called Michael McBane for a second opinion because he is the national coordinator with the Canadian Health Coalition, a public advocacy organization. He too is in Ottawa.

OFF: Well Mr. McBane, you've heard what Tony Clement says that his government is not trying to allow new drugs onto the market faster. What do you make of that statement?

MICHAEL MCBANE (National Coordinator, Canadian Health Coalition): Well I mean listening to his comments it's clear he's in full spin cycle. The reality is that the department's current policy is to speed up drug approvals. We just need to look at the experience in the last number of years where new drugs have been put on the market faster and then later crash. We could think for example of Vioxx is an example under the current system. So when he says we have a stringent licensing procedure currently, that system's broken and it's not protecting us. And there's nothing in this legislation that improves any of the current system. In fact, we argue that it weakens it.

OFF: So is the situation here then that this has been policy and that when he says that he's not changing anything to fast-track it in fact it's already been changed?

MCBANE: The fast-tracking is the previous policy. It predates him as the Minister. What he's doing is providing the legal framework for the speeding up of the approvals so that they don't get regulatory negligence against them, because right now there's a higher safety standard in the Food and Drug Act, the current law has a higher duty of care than

the new proposed law. So he's completing wrong when he says that safety is actually being improved. The standards are being lowered.

OFF: What exactly are the changes in the Food and Drug Act that you believe do allow for drugs to get onto the market faster?

MCBANE: The current policy that's speeding up the approvals is called progressive licensing, and the whole philosophy there is don't wait until you've got the clinical trial safety research conducted because that takes too long. So they're putting drugs on the market that have not been demonstrated to be safe or effective. That's the current policy and they're committed to that. In fact they're signing memorandum of understanding with drug companies to speed up the approvals on the files. And if you're a drug reviewer in Health Canada God help you if you hold up a drug on safety grounds. It's all about speeding up approvals.

OFF: So what are the changes in the act that will support this, what you're calling, this progressive licensing?

MCBANE: The key change is... goes to the core of the statutory duty of the Minister. So the change is that the Minister is now going to establish the benefits outweigh the cost of the drug. So in other words, he's going to be a risk manager and will balance economic interests of a drug against the safety risks of the population. So that's a huge shift in his responsibilities. Previously, under the current law, the Minister of Health has nothing to do with managing risks. The current legal duty is to protect safety. Now they're basically replacing that with economic objectives. So they talk about innovation. They talk about competitiveness as part of the reasons for the change in the law. His mandate should be to ensure the safety of the drugs, period.

OFF: So what about benefits to the consumer? I mean is there... is there nothing... there is going to have to be some risk in order to bring things to people who need them and get the drugs that are available to them faster.

MCBANE: Certainly, there are risks, but I guess what we're looking at here is the legal framework on the duties of the Minister. And we don't think that he should be about the business of being a risk manager.

OFF: Mr. Clement was saying that they are extending the reach into the life cycle of drugs.

MCBANE: Yeah.

OFF: Is that not a benefit?

MCBANE: Well I mean it's interesting with all this language... this is all industry language: life cycle, progressive licensing. We would rather they fix the current system pre-marketing to stop dangerous drugs from getting on the market in the first place like Vioxx rather than finding out there's a problem after thousands of people have been killed. This is what life cycle means. It means if you don't catch the problem when it's in development we catch the problem as you take it and get killed. And that's not good enough.

OFF: He says it's going to be not only monitoring of what happens to people after the drugs are on the market but that hospital monitoring so that if somebody gets sick or goes to hospital because of a drug reaction that they'll know that. Does that exist already?

MCBANE: No, the... if they're going to involve hospitals in monitoring adverse drug events that's a good thing, but we don't want the focus taken off the prevention.

Now the other big problem of course is these new drugs. This is all secret information. Nobody has access to the data. So he's saying that he takes his cue from science that a product is safe. Well actually that's just spin. They won't show us any science in a lot of these products because it's all deemed to be commercial confidential. So the whole system is broken and we shouldn't just be concentrating on dealing with the victims after they get hurt.

OFF: What would principally would you have liked to have seen in these revisions?

MCBANE: Well we need to concentrate more on prevention and establish the safety of a product before it's marketed. And really the only way to do that is to make sure that the data is available to the medical community and to the public. You have to have access to the clinical trial data because right now drug makers withhold the negative findings. There's been stories in the media in the last three weeks almost every week. So we can't have any confidence that any new drug is safe in a secret system. So the first change should be to provide the basis upon which the government decided it was safe to begin with.

OFF: He just said also that the... Canada's moving safety into the twenty-first century and in fact leading the pack, ahead of the world in this. Is that possible?

MCBANE: No, it's the exact opposite. In every international forum that Canada is involved in in terms of health regulation, at the United Nations and at the World Trade Organization, every single meeting Canada is pushing for weaker health protection laws to make them more, what's called, trade friendly, and that includes the Codex meetings in

Geneva, includes discussions with the United States and Mexico on weaker food and drug laws. So obviously the actions of the government of Canada is the complete opposite of the statement of the Minister of Health.

OFF: And just to clarify, you're saying that this all started before the Conservatives became the government.

MCBANE: Oh yes, this has gone back years.

OFF: Alright Mr. McBane, thanks for speaking with us.

MCBANE: Thanks a lot Carol.

OFF: Bye-bye.

MCBANE: Bye.

BUDD: Michael McBane is the national coordinator with the Canadian Health Coalition.