

Minister of Health



Ministre de la Santé

Ottawa, Canada K1A 0K9

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To All P/T Ministers of Health

Dear colleagues,

As Health Ministers, we have the tremendous responsibility of making decisions every day that have direct impact on the lives of Canadians from coast to coast to coast. These issues are often complex, with conflicting opinions on each side about what the right balance of individual responsibility and government action should be.

There is no basis in the *Food and Drugs Act* for the Minister of Health to withhold approval of a drug where the drug is otherwise considered safe and effective for its recommended use. The law does not permit approval to be withheld on the basis of misuse.

In terms of the prescription drug OxyContin, I have heard heartfelt pleas from doctors and patients who speak to the positive impact it has had in treating chronic pain.

And I have heard heartbreaking stories of abuse and addiction destroying the lives of individuals and families.

Both sides of the argument are compelling, and require a response from us as Health Ministers.

During our recent Health Ministers Meeting, the request was made for me to delay approvals of generic versions of OxyContin. At that time, I committed to relay any research you had related to this request on to Health Canada scientists for their consideration. Shortly after our meeting, my officials held a teleconference with your officials to review any research.

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I want to be crystal clear: I do not believe that politicians should pick and choose which drugs get approved. While intentions may be noble in this circumstance, what stops future politicians from caving into public pressure and allowing unproven, unsafe drugs on the market once political pressure starts to mount?

A drug approval process based on politics is a recipe for disaster.

Health Canada will continue its scientific review process of generic versions of OxyContin based on whether the benefits outweigh the risks when used as prescribed and, as always, this will be completed without political interference.

It's important to remember that OxyNeo is, to date, not authorized to make claims that it is "tamper-proof", "tamper-resistant" or "harder to abuse." Health Canada had a panel of experts evaluate the evidence of describing drugs in this fashion, and found that there was insufficient proof to back up these claims.

As Health Ministers, I want to stress that it's very important that we not make health claims that the drug company itself is not legally allowed to say. Doing so runs the risk of confusing public debate on this topic.

Prescription Drug Abuse

OxyContin has certainly garnered much media attention, which makes it a tempting political target that could earn short-term, positive headlines. However, I believe we have the opportunity – and the responsibility – to work together to tackle the issue of prescription drug abuse head-on.

Banning a generic version of one drug would do little to solve the actual problem. There are almost 100 authorized drugs in Canada that are in the very same class of drugs as OxyContin.

Banning all these drugs because they have the potential to be addictive would help dry up the drug supply for addicts, but would lead to pain and suffering for patients who desperately need them.

I am concerned by the tone I have read in recent media reports, in which Minister Matthews from Ontario has said that she envisions that "streets would be flooded" with generic versions of OxyContin if it would be made available. With respect, that could only occur if the provinces and territories, and the medical professions they regulate, let it happen. Generic forms of OxyContin would still be available by prescription only. It is not an over-the-counter drug that can be accessed by the general public. If the country is "flooded" with prescription drugs, it can only be in part because some medical professionals are making it possible.

At our recent Health Minister's Meeting, we spoke about the problem of prescription drug abuse. I believe that this is a critical challenge facing the Canadian healthcare system. Drugs intended for patient care are misdirected, creating health and safety concerns in our communities, destroying families, and costing the system untold millions.

This is a challenge we can tackle together as federal, provincial and territorial governments.

Concrete Action

Starting immediately there are ways we can work together to take concrete action to clamp down on prescription drug abuse. These actions do not require new laws or rule changes; there simply needs to be political will.

OxyContin was approved by Health Canada in 1996 for a limited number of uses. Part of the reason it was abused so much was in part because it was prescribed for conditions it was never intended to deal with, and given out in amounts far greater than was needed.

Under the *Controlled Drugs and Substances Act*, Health Canada can, under certain conditions, remove the ability of doctors, pharmacists and other health care practitioners to provide certain drugs. If you have evidence showing that abuse is happening, bring it forward, and I will take appropriate action.

In addition, Health Canada will, under the *Controlled Drugs and Substances Act*, impose tough new conditions in the licences of dealers allowed to provide products containing the controlled release formulation of oxycodone. Companies will be required to report suspicious and unusual activities, in addition to Health Canada's current requirements to report loss and theft. Health Canada inspectors can and will be dispatched to investigate anything that seems suspicious, and appropriate action will be taken, up to stripping companies of their licence to distribute or sell narcotics. If illegal activity is suspected, Health Canada inspectors will also refer the case to law enforcement.

This is action that can be taken now, and does not need to be limited to forms of OxyContin.

Our government has taken action to crack down on prescription drug abuse in areas of our clear jurisdiction; namely, within Health Canada's First Nations and Inuit Health Branch. Under the Non-Insured Health Benefits program, changes made over the past few years have resulted in a 50% reduction in the amount of long-acting oxycodone provided since 2010 without a significant shift to other long-acting opioids.

These measures include:

- A Prescription Monitoring Program that monitors the use of certain drugs of concern by clients in order to identify and address potential misuse, and to prevent 'double doctoring';
- Establishing maximum monthly and daily drug limits;
- Changing the listing status of extended release oxycodone to exception status;
- Real-time warning (and claims rejection) message to pharmacists at the point of sale; and
- Establishing an external, expert drug and therapeutics advisory committee.

Health Canada is also working to address First Nations prescription drug abuse in Ontario. In addition to these actions, Health Canada is involved in the Canadian Centre for Substance Abuse's great work to help develop a national approach to tackling prescription drug abuse.

My officials can share this information with your officials, and we would be open to hearing what actions you are taking within your jurisdiction to strengthen your monitoring and surveillance of prescription drugs because real action is needed at the provincial level, too.

Provinces can implement rigorous controls that could help shut down abuse within the system. Actions such as prescribing guidelines, trial prescription programs, and product assurance agreements all clearly fall under provincial and territorial jurisdiction.

Also, doctors, pharmacists, dentists, and other medical practitioners all fall under the jurisdiction of provinces and territories. I encourage each of you to speak directly with your provincial and territorial professional medical associations including the Colleges of Physicians, Dentists, and Pharmacists. Make it as clear to them as you did to me in Halifax that you are fed up with prescription drug abuse. Reiterate with them the important role they play in shutting down supply to those who abuse these drugs which are intended to help patients.

Let's work together and share information to help freeze out people who are scamming the system, and stop the illicit flow of prescription drugs into our communities.

Potential Federal Oversight

I believe that this issue can be dealt with while respecting provincial and territorial jurisdiction over healthcare. However, because the Government of Ontario has indicated in the media that provincial and territorial governments may not be able to manage the issue, I am open to considering a greater federal role in overseeing the use of potentially addictive drugs.

If there is consensus that provincial and territorial action is insufficient, then I am open to discussing what level of federal intervention would be appropriate. This could include possible new and/or amended regulatory requirements under the *Controlled Drugs and Substances Act* – for example, regulations that place restrictions on prescribing and/or dispensing practices for potentially addictive drugs in Canada.

However, there is a high risk that creating more bureaucratic hoops for physicians and pharmacists to jump through will have a negative impact on patient care. My strong preference is that we work together to address this issue within existing laws and authorities, alongside medical professionals who are willing to appropriately prescribe and dispense potentially addictive drugs.

Putting Patients First

In closing, I want to remind us all of the most important factor in every decision we make as Health Ministers: patients.

As I mentioned earlier, I have heard compelling accounts from doctors and the patients they care for: people who have lost limbs, people who have survived horrific automobile accidents, people who have been shot; people suffering from chronic pain due to cancer; these are the patients who have used drugs like OxyContin properly to improve their quality of life.

These legitimate patients cannot be forgotten. Indeed, patients like these should motivate us to do the harder work of shutting down prescription drug abuse in Canada.

I want to make sure that whatever we do to crack down on prescription drug abuse does not have unintended negative consequences on those who need this medicine to maintain a reasonable quality of life.

I believe this is a defining moment for us as Health Ministers, when we can show how we can work together and get results that make a difference in the lives of hard-working Canadian families, and their communities.

Sincerely,



Leona Aglukkaq