

CMA's Submission to the Senate Committee on Social Affairs, Science and Technology as part of its study on prescription pharmaceuticals:

Federal levers to address unintended consequences of prescription pharmaceuticals and support public health, quality care, and patient safety

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Submitted by:

Louis Hugo Francescutti
MD, PhD, MPH, FRCPC, FACPM, CCFP, FRCP(Ire), FRCP(Edin), ICD-D, CCPE
President



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The Canadian Medical Association (CMA) is the national voice of Canadian physicians.

Founded in 1867, the CMA is a voluntary professional organization representing more than 80,000 of Canada's physicians and comprising 12 provincial and territorial medical associations and 60 national medical organizations.

CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care.



The Canadian Medical Association (CMA) is pleased to present this submission to the Senate Standing Committee on Social Affairs, Science and Technology for consideration as part of its study on prescription pharmaceuticals in Canada. In this phase, the Committee is studying the unintended consequences of pharmaceuticals, and witnesses to date have identified a broad range of such consequences.

In recognition of the important role of prescription medication in patient care, the CMA has developed an extensive body of policy on pharmaceutical medication and prescribing-related issues, some of which we have shared with this Committee on previous occasions. Physicians are concerned that all Canadians have access to medically-necessary medication that is safe, effective, affordable, appropriately prescribed and administered, and part of a comprehensive, patient-centered health care and treatment plan.

In this brief, the CMA identifies and discusses five issues that are unintended consequences of prescription pharmaceuticals related to public health, quality care and patient safety. These are: addressing shortages in the supply of prescription pharmaceuticals; addressing the abuse and misuse of prescription medication; improved post-market surveillance and reporting tools; supporting optimal prescribing; and, addressing gaps in insurance coverage.

1) Addressing shortages in the supply of prescription medication

Over the past few years Canada's doctors have become deeply concerned about the persistent shortages of prescription medication.

Drug shortages have serious consequences for patient care. For example, if a patient on long-term therapy has been stabilized on a drug which becomes unavailable, and is switched to another drug that produces poorer results, this can lead to a decline in health status. The cost of the substitute medication might be beyond a patient's financial capacity. In some cases a therapeutic alternative may not be available at all.

The CMA has participated on a Multi Stakeholder Working Group on Drug Shortages, with Health Canada, the pharmaceutical industry and health professional organizations, to establish a Canadian drug shortage reporting website. Although a drug shortage reporting website has been established, there is significant room for improvement. While this website may provide information on products in shortage, it is not clear that all shortages are reported, no mechanism for redress is identified, and most importantly drug shortages are persisting.

The CMA supports an investigation into the underlying causes of prescription drug shortages in Canada. One frequently cited reason for shortages is product manufacturing disruptions, such as the 2011 production stoppage at a Sandoz facility in Quebec which resulted in a scramble to find alternate sources of many essential medications. Such disruptions are of

particular concern when the drugs in question have been “single sourced” due to government bulk purchasing policies, and no clear substitutes are available. Therefore, the CMA supports the development of strategies at the provincial/territorial and federal level to discourage single source purchasing decisions.

The CMA continues to call on governments and manufacturers to take meaningful action to address the impacts of shortages including developing appropriate mitigation strategies to reduce the number of drug shortages in Canada and their impact on patient health and patient care.

To support this goal, the CMA recommends that the Committee extend its study on prescription pharmaceuticals to explore the root causes of shortages in the supply of prescription medication in Canada and strategies to mitigate the impacts on patients and patient care.

2) Addressing the misuse and abuse of prescription medication

The use of prescription opioid pain relievers is on the rise, in Canada and internationally. Latest reports indicate that Canada has the second highest per capita consumption of prescription opioids in the world, after the United States. The misuse and abuse of prescription medication is a serious problem and because of its complexity, requires a complex and multifaceted solution.

Canada’s physicians are concerned about the abuse and misuse of prescription medication for a number of reasons. For one, physicians need to assess the condition of patients who request the medication, and consider whether the use is clinically indicated and whether the benefits outweigh the risks. This can be challenging as there is no objective test for assessing pain, and therefore the prescription of opioids rests to a great extent on mutual trust between the physician and the patient. For another, physicians may need to prescribe treatment for patients who become addicted to the medications. Finally, they are vulnerable to patients who forge their signatures or use other illegal means to obtain prescriptions, or who present with fraudulent symptoms, or plead or threaten when denied the drugs they have requested.

Opioid prescription pharmaceuticals are legal products intended for legitimate therapeutic purposes, such as pain management or palliative and end-of-life care. However, they may also be used for recreational purposes or to feed an addiction. It must be recognized that it is addiction which drives the drugs’ illegal acquisition through means such as doctor-shopping, forging prescribers’ signatures, or buying from street dealers or the Internet.

The CMA recommends that the federal government work with provincial/territorial governments and other stakeholders to develop and implement a comprehensive national strategy to address the problem of prescription drug misuse and abuse in Canada. Such a strategy should include:

- a) **Programs to prevent misuse:** The aim of prevention programs should be to reduce both recreational use and inappropriate therapeutic use. Awareness programs and social marketing campaigns could include:
- Information on the benefits and harms of prescription drug misuse, and signs of abuse, addiction or overdose;
 - Instructions regarding safe storage and disposal. This is important since young recreational users frequently report that they obtain drugs from the family medicine cabinet. CMA supports national prescription drug “take back” days, and recommends that patients be educated about the importance of returning unused prescription drugs to the pharmacy.
- b) **Measures to reduce the risk of overdose:** Overdose deaths due to opioid use have grown dramatically over the past ten years. The risk of harm from overdose may be compounded if recreational users are afraid to call for emergency assistance for fear of facing criminal charges. However, opioid overdoses can be prevented with appropriate medication and prompt emergency response.
- c) **Access to treatment services:** A national strategy should also improve patient access to specialized pain management services, and to treatment for opioid addiction. Many believe that if specialized pain treatments were widely available, patients and prescribers would be less likely to rely solely on medication to treat their often debilitating pain.
- d) **A pan-Canadian prescription monitoring program:** Programs to monitor the prescribing of opioids and other controlled substances exist in most provinces, but they vary in quality, in the nature of the information they require, and in the purpose for which data is collected. The CMA recommends that all levels of government work with one another and health professional regulatory agencies to develop a pan-Canadian system of real-time prescription drug abuse monitoring and surveillance. This should include the development of national standards for prescription monitoring, to ensure that all jurisdictions across Canada are collecting the same information in a standard way.

Standardization of surveillance and monitoring systems can have a number of positive effects, including:

- Identifying fraudulent attempts to obtain a prescription, such as an attempt to fill prescriptions from a number of different providers.
- Deterring inter-provincial fraud.

- Supporting professional regulatory bodies actively monitor and intervene, as needed, with practitioners suspected of over-prescribing or over-dispensing frequently-misused medications.
- Finally, supporting researchers gather consistent data to improve our knowledge of the problem, identify research priorities, and determine best practices to address crucial issues.

We are pleased that federal, provincial and territorial health ministries have expressed interest in working together on prescription drug abuse issues, and we hope that this will result in a coherent national system for monitoring and surveillance, and thus to improved knowledge about the nature of the problem and its most effective solutions.

3) Improving post-market surveillance and reporting tools

Health Canada has traditionally approved drugs for general use based on clinical trials that tend to be of short duration and have relatively few participants. As a result, when a prescription pharmaceutical comes on the market there is still limited information about its safety or effectiveness, and there is a need to keep gathering information from people who are using it in “real-world” conditions. As a consequence, adverse drug reactions (ADRs) are all too common in Canada; according to the Canadian Institute for Health Information, one in 200 patients over 65 are hospitalized because of adverse reactions to their medication. As such, CMA once again recommends that Health Canada work to strengthen the capacity of its post-market surveillance system by ensuring that it includes:

- a) Comprehensive processes for gathering drug safety and effectiveness data:** Since most safety data reaches Health Canada in the form of spontaneous adverse drug reaction (ADR) reports, reporting processes should make it easier for physicians and other health professionals to report ADRs voluntarily, by making the reporting system user-friendly and easy to incorporate into a practitioner’s busy schedule. Ideally, ADR reporting could be incorporated directly into the Electronic Medical Record (EMR) as this is developed. Spontaneous reports could be augmented with information gathered through other, more systematic means such as formal post-market studies.
- b) A capacity for rigorous and timely data analysis to identify significant threats to drug safety:** The monitoring and analysis that occurs once an adverse drug reaction (ADR) report has been received are critical elements of the post-surveillance system. Monitoring capacity requires rigorous data analysis that can sort “signal from noise” – in other words, sift through the reports, find the ones that indicate unusual events, investigate their cause, and isolate those that indicate a serious public health risk. It

also requires that the analysis be timely: we note that in 2011 the Auditor General was particularly critical of Health Canada's post-market surveillance timeliness, noting that it could take several years for reports to be reviewed internally.

- c) **Communication of useful information to health care providers and the public:** When new information is uncovered about a prescription drug, it is important that physicians and other health professionals are made aware of it as quickly and efficiently as possible. Therefore, post-approval surveillance requires a system for communicating timely, reliable and objective information to physicians and other health professionals, which they can absorb quickly and incorporate into their everyday practice. Ideally, this communication would report not the safety problem alone but also its implications for their patients and practice: for example, whether some patients are particularly at risk, or whether therapeutic alternatives are available.

The CMA supports the expanded ministerial authorities of recall proposed in Bill C-17, the *Protecting Canadians from Unsafe Drugs Act*, and the intent to address the short-comings of Canada's post-market surveillance system. We will be providing comments on this legislation in the near future.

4) Supporting Optimal Prescribing

In an ideal world, all patients would be prescribed the medications that have the most beneficial effect on their condition while doing the least possible harm. The CMA encourages collaborative efforts toward the achievement of this ideal.

For example, medication misuse among seniors is a major concern. According to a 2011 report from the Canadian Institute for Health Information (CIHI), 62% of seniors on public drug programs use five or more drug classes, and nearly 30% of those 85 and older have claims for 10 or more prescription drugs. Heavy medication use by people over 65 has a number of consequences:

- The risk of adverse drug reactions is several-fold higher for older patients than for younger;
- Medication regimes, particularly for those taking several drugs a day on different dosage schedules, can be confusing and lead to errors or non-adherence; and,
- Patients may receive prescriptions from multiple providers who, if they have not been communicating with each other, may not know what other medications have been prescribed. This increases the risk of duplicate prescriptions, harmful drug interactions and other medication errors.

It is to address such concerns that the CMA developed its 2010 position statement: "A Prescription for Optimal Prescribing This statement recommends that governments at all levels

work with prescribers, the public, industry and other stakeholders to develop and implement a nationwide strategy to encourage optimal prescribing and medication use.

This strategy should include, among other elements:

- a) **Provision of Relevant, Objective Information:** The CMA supports the development and dissemination of information for prescribers that is based on the best available scientific evidence, relevant to clinical practice, and easy to incorporate into a practitioner's daily workflow.

At present, physicians receive much of their information from pharmaceutical manufacturers. Since manufacturers have generous budgets to support their information dissemination, their campaigns are impressive and effective; but their impartiality has frequently been called into question. Objective, evidence-based information to health professionals on prescription drugs and their uses could be disseminated in the following ways:

- Well-crafted online continuing medical education (CME), funded by objective sources.
- Academic detailing, in which teams of experts visit prescribers to provide impartial prescribing advice. Academic detailing programs have demonstrated success; but because they are expensive and labour intensive, it has often been difficult to persuade governments to invest in them.
- Making drug information available to prescribers at the point of care, through such means as mobile phone apps and electronic health records.
- Programs that monitor a prescriber's habits and compare them to those of peers. CMA encourages such programs if their purpose is to educate rather than to enforce a certain behaviour.

Information for prescribers should be augmented by unbiased, up-to-date, practical information for consumers about prescription drugs and their appropriate use.

- b) **Support e-prescribing.** Electronic prescribing has the potential to dramatically improve drug therapy. For example an effective e-prescribing system could:

- List all the drugs a patient is taking, and identify duplicate prescriptions for the same drug from different providers, thus helping to reduce medication error and prescription fraud;
- Incorporate decision-support tools; for example, a warning could appear on the screen if a physician proposes to prescribe a drug that interacts harmfully with another the patient is already taking.
- Improve decision making and communication between providers, providing all of a patient's caregivers access to a common, comprehensive medication profile; and

- Increase convenience for the patient and eliminate illegible handwriting, which is a major cause of medication error.

The CMA recommends that governments, health care leadership and clinical organizations in all jurisdictions commit to make e-prescribing a reality by 2015, and ensure the policy/regulatory environment that supports e-prescribing.

5) Addressing gaps in insurance coverage for prescription medication

Finally, another consequence of the increased role of pharmaceuticals in health care is that, because they are not generally covered by the *Canada Health Act*, many Canadians, particularly those in the lowest income groups, are unable to afford them. Data from the 2007 Community Health Survey estimate that 1 in 10 Canadians does not adhere to their prescription regimes for reasons of cost.

The CMA recommends that governments, in consultation with the life and health insurance industry and the public, establish a program of comprehensive prescription drug coverage to be administered through reimbursement of provincial/territorial and private prescription drug plans to ensure that all Canadians have access to medically necessary drug therapies.

Conclusion

As previously mentioned, CMA has focussed its discussion of unintended consequences on recommendations to support public health, quality care, and patient safety.

The CMA commends the Committee for making this issue the subject of study, and hope that our recommendations, and those of other witnesses, will lead to action to address the unintended consequences of prescription pharmaceuticals in Canada.

Summary of Recommendations

- 1) The CMA recommends that the Senate Social Affairs, Science and Technology Committee extend its study on prescription pharmaceuticals to explore the root causes of shortages in the supply of prescription medication in Canada and strategies to mitigate the impacts on patients and patient care.
- 2) The CMA recommends that the federal government work with provincial/territorial governments and other stakeholders to develop and implement a comprehensive national strategy to address the problem of prescription drug misuse and abuse in Canada.
- 3) The CMA recommends that all levels of government work with one another and health professional regulatory agencies to develop a pan-Canadian system of real-time prescription drug abuse monitoring and surveillance.
- 4) The CMA recommends that Health Canada continue to improve the capacity of its post-approval surveillance system to:
 - Make it easier for health professionals to submit voluntary ADR reports
 - Analyze the data that has been gathered, in a rigorous and timely manner; and
 - Communicate essential information to health care providers and the public in a timely and user-friendly manner.
- 5) The CMA recommends that governments at all levels work with prescribers, the public, industry and other stakeholders to develop and implement a nationwide strategy to encourage optimal prescribing and medication use.
- 6) The CMA supports the development and dissemination of prescribing information that is:
 - based on the best available scientific evidence;
 - relevant to clinical practice; and,
 - easy to incorporate into a physician's workflow.
- 7) The CMA calls on governments to support and deliver funding for impartial continuing medical education programs on optimal prescribing.

- 8) The CMA recommends that governments, health care leadership and clinical organizations in all jurisdictions commit to make e-prescribing a reality by 2015, and ensure the policy/regulatory environment that supports e-prescribing.
- 9) The CMA recommends that governments, in consultation with the life and health insurance industry and the public, establish a program of comprehensive prescription drug coverage to be administered through reimbursement of provincial/territorial and private prescription drug plans to ensure that all Canadians have access to medically necessary drug therapies.