

**CMA Presentation to the Senate Standing Committee  
on Social Affairs, Science and Technology**

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*Prescription Drugs: Clinical Trials and Approval*

Presented by:

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*Check against delivery*

A healthy population and a vibrant medical profession  
Une population en santé et une profession médicale  
dynamique

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The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, 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.

On behalf of its more than 76,000 members and the Canadian public, CMA performs a wide variety of functions. Key functions include advocating for health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 51 national medical organizations.

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Good afternoon. My name is Dr. Maura Ricketts and I am the Director of Public Health for the Canadian Medical Association. The CMA appreciates the opportunity to appear before this Committee today as part of your study of clinical trials and drug approvals.

The CMA represents more than 76,000 physicians in Canada. Its mission is to serve and unite the physicians of Canada and to be the national advocate, in partnership with all Canadians, for the highest standards of health and health care.

Because prescription drugs are an essential component of health care, the CMA has developed a considerable body of policy on pharmaceutical issues. This work can be distilled into one fundamental principle: The CMA believes that our country requires a National Pharmaceutical Strategy to ensure every individual has timely access to safe, effective and affordable prescription drugs. Despite the commitment in the 2004 Health Accord to the creation of such a strategy, Canadians continue to wait for government leadership on this issue. Drugs replace more costly and invasive medical interventions. They are an essential tool in the physician's tool box.

To ensure safety and effectiveness, the CMA also believes in the need for a strong, unbiased, evidence-based system for research and approval. This is at the heart of our commitment to patient-centred care.

In evaluating whether to prescribe a new drug to a patient, a physician will weigh several factors: Does this product offer any benefits over what I am prescribing now? Will it be more effective? Will this new drug be safer? Will it solve any tricky clinical problems, such as drug interactions, or reduce side effects that prevent a medication from being used properly? The physician may also ask: What is the evidence that this new drug is an improvement? Can I trust the evidence? Where can I get access to accurate, reliable information and data on this drug?

Pre-approval drug research must provide answers to these fundamental questions.

## Clinical Trials

I will now focus on two particular issues of concern to practising physicians with regard to clinical trials:

- First, what is being compared to what? Clinical trials may be sufficient for Health Canada's regulatory purposes, but may provide only part of the information a physician needs. For example, is a new cholesterol drug effective on all patients, or only on some of them? Would other patients derive equal benefit from an already existing drug, or from a lifestyle change such as diet or exercise? The CMA recommends that researchers compare a new product to other drugs on the market – and to other interventions, as well.
- Second, is timely, reliable and objective information available on all clinical trial results, not just the positive ones? Canadians need to be informed when a drug has performed disappointingly in trials if they are to make informed decisions about their health care. The CMA, therefore, recommends the results of all clinical trials, not just those with positive results, be made available to health professionals and the public.

I would like to add that the current documentation is not very user-friendly. We recommend that Health Canada prepare summaries of the most essential data, not only for physicians, but for all Canadians to be able to access this information.

## The Drug Approval Process

Turning now to the drug approval process, the CMA believes the following principles should apply:

- The primary criteria for approval should be whether the drug **improves health outcomes** and **offers an improvement** over products currently on the market.
- The review process should be as **timely** as is consistent with ensuring optimal health outcomes and the safety of the drug supply.
- The review process should be **impartial** and founded on the best available scientific evidence.
- The review process should be **open and transparent**.
- Finally, approval of a drug is not an endpoint, but rather one step in that drug's life cycle. It is not uncommon to identify serious safety hazards after a drug has

been approved, because that's when it first goes into wide use. It is important that the approval process be **complemented by a rigorous and vigilant post-market surveillance process**. We look forward to presenting our recommendations on this subject to your Committee at a future session.

Before closing, I would like to briefly address two other matters:

First, the issue of drugs for rare disorders. We are aware that the current clinical trial and approval processes, which place a high value on studies with large population samples, may be unable to adequately capture the value of drugs that are prescribed to only a handful of people. Some patient groups active in the area of rare disorders, such as the Canadian MPS Society and Alpha-1 Canada, have shared their concerns about this with us. These groups, along with the Canadian Organization for Rare Disorders, have been advocating for years for a fair process for evaluating drugs for rare diseases. Because Canada doesn't have a rare disorders strategy, Canadian patients have access to fewer therapies than patients in other developed countries. The issue of how to approve drugs for rare disorders merits closer consideration. The CMA recommends that the federal government develop a policy on drugs for rare disorders that encourages their development, call for ongoing evaluation of their effectiveness, and ensures fairness so that all patients who might benefit have reasonable access to them.

The second matter is that Health Canada's review process provides little guidance on another question which physicians are increasingly asking: Can my patient afford this drug? It is not sufficient that the Common Drug Review conducts reviews of the cost effectiveness of drugs and that provincial/territorial formularies undertake similar studies, as the fact remains that cost is one of the factors physicians need to consider when deciding whether to prescribe a new drug. This is especially true in the case of new biologics, which are very expensive. Canadian doctors believe that the difficulty of making effective prescribing decisions without information about cost needs to be overcome. This only underscores the necessity of a National Pharmaceutical Strategy.

Thank you. We would be happy to answer your questions.