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**Speaking Notes: Kim Steele (BMC Chair) on Canada's Pharmaceutical Sovereignty  
Standing Committee on Health**

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Members of the Committee, thank you. I am here as Chair of the Best Medicines Coalition, a national alliance of over thirty organizations that gives voice to the interests of millions of patients across Canada. I am also with Cystic Fibrosis Canada, a member of BMC.

When we talk about pharmaceutical sovereignty, we often focus on manufacturing, supply chains, strategic interdependence, tariff exemptions and more, all important.

But sovereignty must also address something much closer to our everyday lives: how we get the medicines we need as Canadians to survive and thrive.

Every Canadian needs some form of pharmaceutical coverage.

But Canada's complex, fragmented mix of public and private drug plans undermines sovereignty. We have fourteen "sovereign" public drug plans and over 100,000 "sovereign" private plans. All operate with different rules, formularies, and timelines, making it impossible for Canada to act as a coherent nation, weakening our ability to ensure predictable access to medicines.

If we are to move toward sovereignty, extending similar drug access rights to our own citizens would be a good start.

Much of the current discussion on pharmaceutical sovereignty has focused on essential medicines and generics. While critically important, this focus is incomplete. Innovative medicines—including biologics, oncology therapies, cell and gene therapies, and drugs for rare diseases—are equally essential and must be explicitly included in Canada's sovereignty strategy.

Innovative therapies and clinical trials are often the only treatment options available for people with rare diseases, including rare cancers. Delays at any stage—regulatory review, clinical trial start up, health technology assessment, or reimbursement—can mean missed treatment windows, irreversible disease progression, and premature death.

Cystic fibrosis provides a stark example.

Trikafta is a life changing therapy that benefits more than 95% of the Canadian CF population. Within two years of access in Canada, days in hospital were reduced by nearly 40 per cent, home IV antibiotic use by 60 per cent, and lung transplants by almost 70 per cent.

And yet, this transformational therapy came to Canada two years after people in other countries got it.

Why?

Because prolonged uncertainty around proposed pricing reforms delayed the manufacturer's decision to launch in Canada. While patients elsewhere got better, Canadians waited. They became sicker. And we lost some who were waiting for this medicine to come.

These experiences are not unique to cystic fibrosis. When it comes to access to medicines in Canada, uncertainty is everywhere.

Pharmaceutical sovereignty is not achieved through good intentions. Countries that take sovereignty seriously rely on clear laws, regulations, and incentives to ensure medicines are developed, launched, studied, and supplied in their countries. That predictability enables patient access and signals to innovators that a country—and most importantly its people—are worth investing in.

The U.S. Orphan Drug Act is a powerful example. Implemented in 1983, it established market exclusivity, tax credits, grants, priority review, and the elimination of FDA application and user fees for orphan drugs.

Another US initiative is the transferable priority review voucher, which accelerates access to future therapies. If used in Canada, these may have helped close the access gap to Trikafta and many other innovative therapies.

These incentives were written into law, and they have transformed rare disease drug development throughout the globe.

Ironically, some of the therapies developed under that framework are the same ones Canadians can't access because we have not implemented similar initiatives.

If Canada wants innovative medicines to be developed, studied, and accessed here, we need laws and policies that actively support patient access.

**At a minimum, pharmaceutical sovereignty must deliver four things:**

- 1. a reliable and continuous supply of medicines across all therapeutic areas**
- 2. timely access to innovation, including faster regulatory approval and market access**
- 3. equitable access across jurisdictions and payer types and**
- 4. system resilience so Canada remains an attractive environment for research, clinical trials, and life sciences investment.**

Pharmaceutical sovereignty is not an abstract economic concept. It is about whether Canadians can stay healthy, participate fully in society, and trust that the medicines we need will be there when we need them.

On behalf of millions of patients across Canada, thank you. We encourage you to keep patient access, equity, and lived experience at the centre of this study.