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Access to New Medicines: What Should Ottawa Learn from COVID-19?

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Introduction

COVID-19 has been and continues to be a stress test for our health system and everything in, around, and over Canada's leadership. This pandemic crisis is spotlighting significant concerns about Canada's health system that for too long have been overlooked or known but no politician or government official has dealt with them. The current focus of governments, including Canada's, is naturally dealing with the pandemic response and recovery after what can only be described as a slow and poorly coordinated start. This seemed to stem from a lack of preparedness, despite Canada having endured the SARS epidemic in 2003 and H1N1 epidemic in 2009, and poor information systems that do not provide sufficient and timely data about the extent of the spread of the virus, leaving Canadians vulnerable to further waves of infection (Tasker 2020).

Let us hope that we don't fail once again to adopt the robust pandemic responses that will protect us better next time. But let us also take this opportunity to finally focus on some of the problems plaguing the broader system that are keeping sick and dying Canadians from receiving the latest treatments, tests, and vaccines in this country. And most importantly, let us

avoid some bad ideas that will make access to medicines worse in Canada, not better. As the world races to rebuild supply chains, and find new treatments and vaccines amid the COVID-19 pandemic, Canadians risk being left behind.

Health "Care" System

Canadians are frequently told and many believe that we have one of the best health care systems in the world, despite many illustrations that this is not so (Picard 2016). COVID-19 is yet another demonstration that this is untrue in too many ways. Certainly, Canada has dedicated health care providers, including physicians, nurses, pharmacists, technicians, researchers, and other workers. But there are significant deficiencies in facilities, resources, data systems, case management, and leadership.

COVID-19 presents an opportunity to consider what Canadians want from their health care system, what they want it to look like, and the way they want it to perform in the future.

The devastation of seniors and workers in long-term care facilities is a big failure for our preparedness. We may well have spared our hospitals and their intensive care units from being overrun in the short-term, but at what eventual cost of the medium-term consequences of delayed surgeries, tests, and emergency department visits and the long-term economic, social, and mental health impacts?

The current health care system is based on a model applicable more than 50 years ago. Who drives a car or uses a computer made 50 years ago? The health insurance system was designed to protect patients against the financial impacts of major health events for which acute treatment took place mainly in the hospital setting. The physical infrastructure, service delivery methods, provider incentives, and flow of information used in the 1960s to 1980s were appropriate to that time, but today these decades-old foundations are outdated and act as barriers to more effective health care. For example, much of the care administered in hospitals in the past can and should be delivered in the community or the patient's home.

Another example of these barriers is the old system's unreadiness and, in some ways, unwillingness to embrace the new era of cell and gene therapies, such as immunotherapy that uses T-cells (part of the body's immune system) from the patient that are specially altered and returned to the patient to treat some cancers (Newick et al. 2017). These can cure profound diseases and be once and forever solutions.

Some Canadians still believe in the status quo, but the vision of Canadians about what their health care system should be is often inconsistent and not clearly expressed. The system's objective should be to promote and deliver sustainable solutions to maintain the health and welfare of Canadians

throughout their lives. Sustaining the existing system is not the same as sustaining patient lives.

Unfortunately, ideology often gets in the way. Canada made a decision many years ago that its health system would be funded mainly through public resources, which has resulted in for-profit services' being largely excluded.

Although public resources can be channelled through public or private delivery to achieve health care goals, European experience demonstrates that private services within publicly financed systems can be highly effective and reduce barriers to innovation. Canada is locked into policies established in the *Canada Health Act* that inhibit even partial cost-sharing with patients in most health care circumstances. As a result, Canada has a relative scarcity of hospital beds, physicians, and equipment (Barua and Moir 2019), despite ranking among the most expensive health care systems in the world. Its health system struggles to address routine health care needs even in ordinary times, let alone trying to develop resources or a surge capacity for events such as the pandemic.

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Regrettably, neither the current nor previous federal governments seem to have heeded these needs and little in the pandemic plan was put into action to deal with COVID-19. It is perhaps not surprising because public health is the poor relation of the health system.

Our system is predominantly one for the sick in that its principal purpose is to help Canadians once they are ill, with much less attention given to prevention. When a doctor declares an emergency for a patient, resources are usually available with relatively few limits. By contrast, resources devoted to preventative health are only a tiny fraction of those given to dealing with illness. For example, only 2.2 percent of Ontario's operating budget for health services goes to "population and public health programs" (Ontario 2019) compared with nearly 90 percent to Local Health Integration Networks, service providers, and health insurance (the Ontario Health Insurance Program), although the latter includes the work of family physicians in promoting and maintaining health.

No one should be surprised by this situation. Politicians tend to see putting money into visible outcomes as being a more likely election-winning strategy than devoting resources to help prevent or contain future problems, such as care for the wide spectrum of the population (e.g., seniors, Indigenous, disabled, and palliative), the epidemics in cancers, diabetes, high blood pressure, and obesity, or potential future pandemics.

As we face the disruption of global supply chains for medicines and medical equipment during COVID-19, governments need to stimulate the manufacture of resources critical to quality health care in Canada. And Canadians need to be willing to pay the full costs of preparedness and security of supply.

Medicines

The basic active ingredients of most medicines used in Canada today are produced in China and most of the finished products are made in India (Powell 2020). This is the result of all major brand-name and several generic pharmaceutical manufacturers' being global commercial companies with headquarters based outside of Canada, predominantly in the United States, the European Union, or Japan. These global conglomerates have chosen to have their products made in China and India because it keeps costs down in two ways: cheaper labour expenses and reduced expenditures resulting from lower environmental standards. Our federal and provincial governments have looked the other way about these issues in their desire to move towards rock-bottom drug prices.

> *Canadian patients are dependent on extended global supply chains' being uninterrupted.*

Not even packaging for sales in Canada is necessarily done in Canada. Consequently, Canadian patients are dependent on extended global supply chains being uninterrupted not only by crises like COVID-19 but also by governmental policies, labour unrest, transportation disruptions, and acts of politics or God. Although there may be limits on what the Canadian government can do to alter this situation, it is critical that the government does not get in the way of the process and that it does everything it can to protect and foster robust innovative and generic medicine companies' presence in Canada, including encouraging small startups that can be among the most ground-breaking.

As the federal government failed to recognize and respond nimbly to the early warning signs of COVID-19, could it be that it is similarly missing the early warning signs of coming trouble in access to new, breakthrough, life-saving, or life-altering medicines?

What is happening in the real world outside federal and provincial capitals that could be those early warnings? For example, are applications for new drugs in Canada increasing or decreasing? Are applications for new clinical trials

at Canadian sites – which give patients early access to promising therapies – increasing or decreasing?

As we will discuss in more detail below, Canadians should be concerned about the government's intention to introduce significant changes to the tribunal that sets price controls for new drugs in Canada, which will drastically reduce the prices of new and old medicines and will diminish Canada's attractiveness as a country in which to launch new products, delaying or denying access to Canadians. This will include vaccines (Rawson and Koester 2020), which is particularly concerning when we are all waiting for a COVID-19 vaccine.

Is There a Yellow Brick Road to Patient Access?

First, let's be clear. Canada already has barriers that deter drug developers from bringing new medicines here (Rawson 2018). The first kilometres in what can be a long journey start with Health Canada's regulatory review, which assesses the efficacy, safety, and production quality of the new drug. The time taken for the marketing authorization review in Canada is similar to that in Europe and the United States. Yet, because pharmaceutical manufacturers place Canada lower than the United States and Europe in their global launch plans, submissions to Health Canada are usually filed after those to the US Food and Drug Administration (FDA) and the European Medicines Agency, leading to later authorization in Canada. So Canadian patients are already, in most cases, late to obtain new therapies.

Once a drug has received marketing authorization from Health Canada, the manufacturer faces more kilometres on the long road of having the drug covered by public and private plans. About two-thirds of Canadians receive drug insurance coverage (Sutherland and Dinh 2017) through private insurance paid for by individuals or cost-shared with employers, unions, or associations and another 40 percent have some degree of coverage through federal, provincial, and territorial government-funded plans. Government plans are mainly designed to fill the gaps by providing insurance to seniors, social assistance recipients, and some special groups, such as children, cancer patients, or when costs are deemed to be catastrophic. Only the province of Quebec has a mandatory, mixed public-private, universal drug plan where every person is insured.

To be considered for reimbursement in Canada's public drug plans (except Quebec), drug developers submit a health technology assessment to the Canadian Agency for Drugs and Technologies in Health (CADTH) to demonstrate the value of the drug based on the clinical benefit of a drug in relation to its cost, i.e., its cost-effectiveness. Quebec has its own health technology assessment agency, Institut national d'excellence en santé et en services sociaux (INESSS).

CADTH claims to be an independent organization on its website and in publications, but Canadians should be made aware that it is owned, managed, and funded by federal, provincial, and territorial health ministries and therefore does not operate at arm's length from governments (Rawson and Adams 2017). Its board is controlled by deputy ministers of health. It operates outside of parliamentary oversight, exempt from public forms of accountability through the auditor general and *Freedom of Information* rules. Its deliberations take place behind closed doors. Thus, there is a glaring contradiction in CADTH. It is a private entity that does the work of governments, is funded chiefly by governments, and is governed by a majority of government representatives, although it is not subject to any standard of public accountability.

Consequently, its processes and recommendations do not adhere to the good governance principles of accountability to all Canadians, transparency for all concerned (some stakeholders have greater access to information than others), participation by all stakeholders (patient participation is limited), equity (all stakeholders should have opportunities to improve or maintain their well-being), responsiveness (all processes should serve all stakeholders), and consensus building to reach a broad consensus on recommendations.

> *The pCPA is designed to capitalize on the combined governments' buying power.*

CADTH has two separate processes for drug reimbursement recommendations: one for cancer therapies and the second for all other drugs. At around 80 percent, positive recommendations for oncology drugs (Rawson 2014) are significantly higher than the rate of 50-55 percent for other drugs (Griffiths et al. 2015). As a comparison, positive recommendations from the National Institute for Health and Care Excellence, which assesses all new oncology and most other new drugs for reimbursement in England's publicly funded National Health System, are reported to be 76 percent (ibid.). Most positive recommendations from CADTH are for medicines to be listed with clinical criteria (these can be restrictive with or without input from relevant specialists) and/or a need for a price reduction.

Following a CADTH review, the next milestone for pharmaceutical manufacturers seeking public coverage for their drugs is to gain admittance to the negotiating process established by the federal, provincial, and territorial governments, known as the pan-Canadian Pharmaceutical Alliance (pCPA). A positive CADTH or INESSS reimbursement recommendation does not guarantee that price negotiations will begin for a drug. The pCPA decides whether to open a negotiation. If successful, the negotiation determines both the cost and

criteria under which governments will pay for a drug and concludes with a Letter of Intent (LOI) to fund the drug. The LOI is not binding on governments.

The pCPA is designed to capitalize on the combined governments' buying power, with the objectives of increasing access to drug options, achieving lower drug costs and consistent pricing, and improving consistency of patient-use criteria across Canada, although the cost-containment objective seems dominant. Like CADTH, the pCPA is owned, funded, and governed by the federal, provincial, and territorial governments. Over the past few years, CADTH and the pCPA have become closely aligned (Rawson 2020a). An objective of the alignment appears to be to ensure that a negative recommendation from CADTH results in no pCPA negotiation and a positive one sets up negotiating factors between the pCPA and manufacturer, usually the need for a substantial price reduction and/or limits on patient coverage.

> *A drug successfully negotiated through the pCPA is not the end of the road.*

A drug successfully negotiated through the pCPA is not the end of the road. It is reviewed yet again by each individual federal, provincial, and territorial government for its potential budget impact on their drug plan and any implementation issues. Often these reviews involve the same officials who negotiated under the pCPA umbrella. Again, a pCPA LOI does not guarantee that all plans or, indeed, any plan will provide coverage for the drug. Manufacturers must negotiate on the basis of the LOI with each public drug plan, which is free to negotiate further discounts, rebates, criteria, or other conditions with the manufacturer beyond those in the LOI before including the drug in their formulary or refusing to cover it.

Provincial drug plans have complex systems of deductibles, copayments, and premiums, and for many drugs, special or restricted access criteria can result in wide variation in patient eligibility, out-of-pocket expenses, or where the drug can be administered (e.g,. hospital versus home), each of which can impede patient access and negatively affect their health outcome. These wide variations are sometimes referred to as the postal code lottery for patient access.

Access restrictions based primarily on cost-containment can increase the potential for a negative impact on patient health outcomes. For example, the impact of Quebec's restrictive access to clopidogrel (Sheehy, LeLorier, and Rinfret 2008), an anti-platelet agent that reduces the risk of thrombosis (a complication often resulting in death) following coronary intervention with stenting, was associated with 20 percent of patients either not receiving the drug or receiving it after a delay, which increased the risk of mortality from all causes.

As we can see from the details above, for a new drug to get past the regulatory review, health technology assessment, and two-tiered pricing negotiations, it is a long road that can take at least two years. For instance, sapropterin (Kuvan), a drug used to treat phenylketonuria (a brain-threatening disorder in which the body cannot break down an amino acid that, if untreated, leads to mental retardation), received marketing authorization in Canada in April 2010. After three submissions to CADTH, the drug received a positive, conditional reimbursement recommendation in January 2016 but the pCPA pricing negotiation was completed only in March 2020 and the drug is listed in only three provinces. Patient access is incomplete after 10 years of process upon process.

Patients, families, and clinicians have a right to be impatient about this process of processes.

PMPRB New Regulations – More Price Controls

To this already complex process, the federal government will soon be adding changes to something called the Patented Medicine Prices Review Board (PMPRB) that will radically reduce the prices of new medicines in Canada, not by negotiation but by federal regulation, and could have a dramatic effect on access to new medicines.

The PMPRB can already delay access to new beneficial medicines, with sometimes deadly results. For example, patients and their families encouraged the manufacturer of edaravone (Radicava) for amyotrophic lateral sclerosis (a lethal neurodegenerative condition that results in progressive muscle paralysis and a life expectancy of three to five years after diagnosis) to apply for marketing authorization in Canada. The drug received authorization after a priority review by Health Canada in October 2018 (Breiner, Zinman, and Bourque 2020) because clinical trial evidence showed it slows this disease. CADTH gave it a conditional positive recommendation in March 2019 and a pCPA price negotiation was completed in April 2020.

However, the PMPRB and the manufacturer could not reach an agreement on the list price. The developer's route around this blockage has been to withdraw its patent for edaravone in Canada so that the drug no longer comes under the mandate of the PMPRB. Instead of relying on patent protection, the company appears to be trusting in the eight years of data protection that comes with Health Canada's marketing authorization. This business strategy may work in this instance, but other manufacturers could simply decide that the Canadian regulatory environment is too challenging and market their products elsewhere.

For the past 30 years, the PMPRB has regulated manufacturers' list prices. Price ceilings were set by referencing a group of countries featuring a balanced rep-

resentation from high- and low-priced markets. The new proposed guidelines change the reference countries so that the benchmark is now biased, because the group of 11 countries is stacked with lower-priced jurisdictions. The PMPRB says that the high-priced countries (the United States and Switzerland) are to be removed because they differ from Canada regarding price controls, GDP per capita, and population. However, the United States and Switzerland are as similar to Canada as Sweden and France, which remain in the group of 11 countries, and as Norway, which is an addition to the group.

The PMPRB will go further in regulating prices by using new factors, including pharmacoeconomic methods to calculate a cost-effectiveness threshold representing the upper limit of the public health care system's willingness-to-pay for a new drug. Willingness-to-pay has been set by the PMPRB in draft guidelines at $60,000 cost per quality-adjusted life year gained from using the drug. This threshold is the regulator's subjective view of the value of a human life. This type of analysis is used in Canada and other countries to inform reimbursement negotiations but not for price regulation. Pharmacoeconomic analyses are entirely inappropriate for calculating definitive, prescriptive, and legally enforceable price ceilings, because they are based on data and methods for which no agreed standards exist, producing, at best, subjective estimates that depend on the assumptions made in the calculations.

> *"PMPRB regulations together are like a doctor saying, "Start four new drugs on the same day.".*

The draft guidelines would also control drug developer profits by cutting prices of drugs with total market sales exceeding $25 million annually. The sales thresholds and associated mandatory reductions are purely arbitrary.

These new factors for controlling prices are not being used by any other government in the world to regulate drug prices.

No medical doctor would prescribe four different drugs for a patient to start taking all at the same time. If something fails or goes wrong, how do you identify the cause of the problem? Each drug should be introduced on its own and the patient watched for effects and side effects. Yet, the PMPRB regulations together are like a doctor saying, "Start four new drugs on the same day."

Consequently, those regulations constitute a risky experiment in public policy, while the health and lives of patients hang in the balance. In particular, any patented therapy or vaccine for COVID-19 will be required to comply with new PMPRB regulations and guidelines in place at the time of their launch in Canada.

These complex changes and proposed guidelines will be enabled by regulations first scheduled to take effect on July 1, 2020, although retroactive to August 2019. The take-effect date has now been moved six months to January 1, 2021, without a change in the date of retroactivity. Although the guidelines could be revised – a revised draft is expected in the week of June 15, 2020 – past experience with such consultations has shown that the PMPRB tends not to listen to criticism and tries to proceed with what has already been planned.

So, we all have a pause in regulatory change. Will the government use the time for careful reflection or sober second thought?

The PMPRB and Health Minister say lower prices will not affect the availability of new drugs (Cooke 2020). But this is unrealistic, and repeating talking points is not the same as evidence and analysis (Rawson and Adams 2020). Several case studies have shown that the new PMPRB regulations have the potential to lead to mandated price reductions from manufacturers' listing prices of 45 percent to 75 percent and perhaps more (Rawson and Laurence 2020a). Reductions of this magnitude are unsustainable for business and have the potential to negatively affect sales in other countries due to international comparisons. The planned changes fly in the face of an enormous amount of literature concerning the negative consequences of price controls on the drug supply and drug research and development.

Patients might like cheaper drugs and drug insurers certainly want them. However, while tighter pricing policies provide savings in the short term, they come with social and health costs. These costs include significantly reduced or much delayed introductions of new drugs, a negative impact on health outcomes and life expectancy, and a reduction in pharmaceutical company investment, patient support programs, basic research, and clinical trial support and employment (Moreno et al. 2017).

The first warning signs have already appeared:

- The number of clinical trials registered in Canada between November 1, 2019 and March 15, 2020 fell by 52 percent compared with the same period in previous years (Rawson 2020b).
- The percentage of new drugs approved in Canada before or within a year after approval in the United States decreased substantially from an average of 55.4 percent between 2013 and 2016 to 15.6 percent in 2019 (Rawson 2020c).
- Twenty-five novel therapeutic medicines authorized for marketing in the United States between October 2019 and February 2020 have not been submitted to Health Canada.

Is anyone in the federal government paying attention to these early warning signs?

The PMPRB changes have led to significant uncertainty and concern regarding Canada's pharmaceutical environment among manufacturers and distributors and will lead to delays in launching medicines in Canada or not bringing them to Canadian patients at all, or, in the case of two new drugs for breast cancer, withdrawing them from the Canadian market. Drug developers have clearly stated their unhappiness with the changes at the PMPRB. In a survey of senior Canadian and global pharmaceutical executives regarding the pricing changes, all respondents reported these would negatively affect their overall business plans in Canada, and almost all thought that they would negatively affect product launches, employment, and clinical research here (Life Sciences Ontario 2020). Manufacturers have also expressed their concerns in the recent consultation on the PMPRB draft guidelines – all responses from companies and their associations ranged from concerned to downright negative.

> *Drug developers have clearly stated their unhappiness with the changes at the PMPRB.*

Most submissions to the consultation from patient groups also indicate that patients are worried that the new regulations will lead to poorer access to new drugs in Canada. Patients expect manufacturers to market their products at reasonable prices, but they also expect the government to ensure that the regulatory environment does not limit access to new life-saving treatments (Grover and Chilvers 2020). Furthermore, provincial cancer agencies commented in their submission that the new guidelines are complex and disagreed with the proposed $60,000 per quality-adjusted life year, saying it should be $100,000-$120,000 for oncology drugs, with higher exceptions for rare cancers (CAPCA 2020). The association also expressed concern that the price controls would mean less funding from drug developers for clinical trials and clinical and patient support programs. In addition, the Public Health Agency of Canada (2020) expressed concerns about vaccines' coming under the PMPRB's pricing guidelines, which is particularly worrisome when the world urgently needs COVID-19 vaccines (Rawson and Koester 2020).

Alarm has also been raised internationally. The office of the United States' Trade Representative has stated concern about Canada's plan to change how it calculates the fair price of prescription drugs and placed Canada on a "watch list" (McCarten 2020).

Again, we ask: Is the federal government paying attention to these warning signals and concerns? Perhaps current learnings about what happens to the price of personal protective equipment in the COVID-19 pandemic when it is in short supply and manufactured overseas may prompt a postponement of the new regulations and sober second thought?

National Pharmacare and Canada Drug Agency

The federal government intends the PMPRB changes to be a step toward a national pharmacare program. A majority of Canadians support the concept of national pharmacare and many believe it should be a single public-payer system.

Although the kind of program they visualize diverges widely, most see national pharmacare providing more comprehensive drug coverage than the current provincial and federal programs do. However, some academics, endorsed by many of their colleagues and labour unions, have encouraged the federal government to introduce a limited program covering "essential medicines" and strong cost-containment (Taglione et al. 2017). They believe that a proportion (up to 20 percent) of Canadians cannot afford basic medicines, such as antibiotics and heart and respiratory medications. In fact, the proportion of Canadians who cannot afford basic medications is small and all provincial public drug plans have a safety net to cover necessary drugs for low-income Canadians. For unclear reasons, some individuals do not apply although eligible.

The cost of national pharmacare is likely to be expensive. The Parliamentary Budget Officer estimated the annual cost, using generous but unrealistic assumptions, to be $19.3 billion (Canada 2017). Based on more appropriate assumptions, the Canadian Health Policy Institute (2020) produced an estimate of $26.2 billion. The Liberals' own Advisory Council on the Implementation of National Pharmacare put the cost at $40 billion (Canada 2019a), while the tax consulting company RSM Canada projected the cost to be $48.3 to $52.5 billion (Canadian Taxpayers Federation 2019).

However, it is concerning that there are clear indications that the federal government, at least initially, plans a limited national formulary that will cover only some medicines commonly used in primary care. What if you need specialized care with specialized drugs? The risk here is that any extension to coverage planned for later will not occur or be long delayed, especially following the huge debts incurred by governments as a result of the COVID-19 pandemic.

There is also a question of fairness. Will Canadians find it fair if federal politicians and officials, who have high-quality private health insurance that covers more than 10,000 medicines for themselves and their dependants (Rawson and Adams 2019), provide them with a national pharmacare program that covers a few hundred or even a couple of thousand drugs? Or will patients and other voters see it as hypocrisy? In the drug plans for the thousands of federal employees and their dependants paid for by taxpayers, Canada already has a model for national pharmacare – shouldn't all Canadians have this benefit?

New restrictive price controls, a long and winding road to drug access with many hurdles (Rawson and Laurence 2020b), and parsimonious pharmacare

programs lead drug developers to delay or decide against launching products, and even when they do secure regulatory approval, they sometimes let it lapse or choose not to pursue marketing. This leads to limited choices of medicines, which can have an adverse impact on health outcomes.

The COVID-19 crisis is not the time to be drastically increasing the pressure on drug prices. The federal government should at least delay and preferably halt the new stringent PMPRB price regulations, especially the new factors, as well as plans for national pharmacare. Instead, the government should be doing everything it can to foster robust industries for innovative medicines, medical devices, and personal protective equipment in this country. Canadians are unlikely to look kindly on politicians and officials whose policies hinder Canada's becoming an early adopter of any vaccine, new therapies, or new tests against COVID-19.

The federal government also plans to introduce a new Canada Drug Agency that will assess the effectiveness of new prescription drugs, negotiate prices on behalf of Canada's public drug plans, and recommend which drugs represent the best value for money for Canadians to identify those for the planned national formulary (Canada 2019b). Although little is known about the government's intentions beyond high-level statements, the implication appears to be to amalgamate the health technology assessment agencies (CADTH and INESSS) with the pCPA and may include some aspects of the work of Health Canada in evaluating and regulating the benefits and risks of new medicines.

The current system could be described as a steeplechase in which a series of fences must be jumped over. The planned Canada Drug Agency could provide a smoother method of negotiating the fences. However, it also has the potential to replace the fences with a high assault-course type of wall because the intent seems to be to deter manufacturers wanting to sell high-value drugs in Canada, such as cell and gene therapies.

Conclusion

The COVID-19 pandemic could teach Canada's governments and citizens numerous lessons if citizens demand and governments allow a thorough, public, and independent inquiry into how the country responded better than such countries as the United States, Spain, and Italy but not as well as Taiwan, South Korea, Vietnam, Australia, New Zealand, and others. The process should review the whole health care system to move its model into the twenty-first century. Perhaps we can start by banning the use of non-electronic fax machines, which hospitals, health care providers, and pharmacies still use to communicate about patients?

Evidence already exists that management of supplies is deficient and the current limited technology used to administer and evaluate the system is

outdated. Despite reductions in the time spent in hospital and increasing use of day surgery, there are many further opportunities for more acute care to be delivered in doctors' offices or at home. Telemedicine advanced more in the last two months than in the previous 10 years. The siloed management of the system in which hospital, physician, and pharmacy services are managed by separate government branches with little integration should also be updated to a holistic approach.

Prime Minister Trudeau's statement about "protecting Canadians" prompts skepticism when his government is making changes to the pharmaceutical environment that will decrease Canada's attractiveness to manufacturers as a place to perform research and launch new medicines, which, in turn, will reduce Canadians' access to products that could ease their suffering and extend their lives. Canadians need the opposite. The federal government should be stimulating access to innovative medicines by encouraging a pricing system that accounts for technological advances, promotes research and development, and secures access to novel drugs in Canada.

Drugs frequently help keep people out of hospitals, which, as the COVID-19 pandemic has demonstrated yet again, are a limited and fragile resource. Drugs contribute to sustainability of both patients' lives and the health system. Canada needs to learn where the weaknesses are that have been exposed by the pandemic to build a more resilient health system, which includes access to new innovative medicines, even if they are costly. Moving a deadly disease, such as amyotrophic lateral sclerosis (ALS), from untreatable to treatable is worth a lot. Moving a disease from treatable to curable is worth a lot more. Miracle drugs are of benefit only if patients and their doctors can access them.

About the authors

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John Adams is a seasoned management consultant with a current focus on advocacy for unmet patient health needs. He has extensive experience in public policy, governance and senior management.

He volunteers as the Board Chair of the Best Medicines Coalition (BMC), a national non-profit of 27 patient organizations, which together represent millions of Canadian patients. The mission of BMC is to help ensure timely access to medicines that meet patient needs and that are safe and effective. BMC is engaged in current issues of national pharmacare, drug supplies and shortages, COVID-19 issues including therapeutic scams, price controls on medicines, health technologies assessment and regulatory reform.

Previously he served ten years on the board of the Canadian Organization for Rare Disorders. He has a son with a rare genetic disorder phenylketonuria (PKU) which is a brain-threatening disorder and is co-founder and President of both a Canadian non-profit and a global charity for that rare disease. That son participated in a clinical trial for the first drug to treat PKU, and is an example of a person outside the USA who benefits from the US Orphan Drug Act.

He graduated from York University in Toronto with a degree in political science,1970; first worked as a reporter for The Globe and Mail, 1971-1975; then as chief of staff to an Ontario Cabinet Minister (1977-1981), was elected to Toronto City Council three times (years 1991-2000) including serving as Budget Chief (1993). His track record includes being the only Budget Chief in+ 60 years to reduce property taxes in Toronto. While on Council, he served on a large number of boards, including Toronto Public Health, Toronto Economic Development, Toronto District Heating Corporation, Toronto and Region Conservation Authority, Toronto Harbour Commission and as a trustee of Canada's largest health sciences centre, University Health Network.

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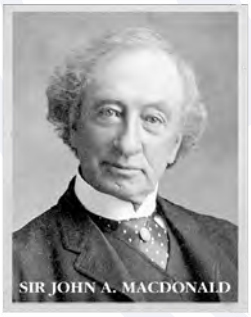
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