



A Prescription for Better Medicine: Why Canadians need a national pharmacare program

Acknowledgements

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INTRODUCTION

In modern health care, appropriately used prescription drugs are an essential component to health and well-being. The World Health Organization (WHO) has declared that all nations should ensure universal access to necessary medicines through pharmaceutical policies that work in conjunction with broader systems of universal health coverage.¹ The gaps in our current system exacerbate inequalities rather than prevent them, as “Canada’s health care system is not the universal equalizer we like to think it is.”²

We regularly hear stories of big pharmaceutical companies – “Big Pharma”

– increasing prices on lifesaving medications and patients suffering the consequences of this unfettered greed. It is time to bring Canada’s drug coverage into the 21st century and ensure drug coverage for everyone – a system that puts people before profit. Canadians across the country know that a universal, national drug coverage plan – also known as pharmacare – is long overdue. It is time for the federal government to carry out Tommy Douglas’ vision of equitable, safe and effective drug coverage for everyone.

The discussion over a national pharmacare program is inspired not only by

the important cost savings a program would bring, but by the need to actualize the right to universal health care for everyone in Canada. This fundamental cornerstone of our medicare, which values need over ability to pay, is still as important today as it was over a decade ago. No one should have to choose between buying food for their family, paying rent or getting the medications they need. All Canadians deserve equal access to safe and effective medically necessary drugs. It is time to finish writing the final chapter in medicare’s story.

AN UNFINISHED STORY

Canada has the unique distinction of being the only country with a universal national public health care plan not to include prescription drug coverage. Beginning in the post-war years of the 1940s, many similar countries introduced national drug plans into their health care systems to address the inadequate drug coverage for their citizens. In these countries, three generations have now benefited from their governments implementing pharmacare. Meanwhile, Canadians continue to pay increasing prices and have less access to the medications they need.

A national drug coverage plan was first recommended in Canada by the Royal Commission on Health Services in 1964. It was known as the “Hall Commission” after its chair, former Saskatchewan Supreme Court Justice Emmett Hall. Justice Hall argued that, “in view of the high cost of many of the new life saving, life sustaining, pain killing, and disease preventing medicines, prescribed drugs should be introduced

as a benefit of the public health services program.”³ Yet, to this day, pharmacare remains one of the core pieces missing from our medicare system.

Since then, there have been multiple recommendations that consistently call for universal drug coverage – from the National Health Forum under Jean Chrétien in 1997 to the Romanow Commission in 2002.⁴ The Romanow Commission made the specific recommendation that all governments in Canada work together to integrate medically necessary medication into the Canada Health Act, which would create national standards for universal access. Importantly it “specifically recommended that a National Drug Agency be created to coordinate a wide range of pharmaceutical policies, including evaluating new drugs, negotiating drug prices and coverage decisions, monitoring of drug safety and electiveness, and providing information to patients.”⁵ Yet despite the ever-increasing evidence and calls for policy changes, little progress has

been made to establish universal pharmacare for Canadians.

Medicine used in acute care at hospitals is 100 per cent publicly covered in accordance with the Canada Health Act, but there are no national standards for coverage of prescription drugs outside of hospitals in Canada. The federal government has jurisdictional responsibility for regulating pharmaceutical products, regulating pharmaceutical marketing and setting intellectual property rights and related policies that affect the availability, price and use of medicines. Since the provinces bear the majority of the resulting costs from federal policy, there is often friction between the two levels of government.⁶

The fact that health policy reformers at both levels of government, health care advocates and the public continue to put forward the idea of universal pharmacare shows there is strong passion for better and more equitable medicare in Canada. It shows that we will not give up on a good idea.⁷

THE CHANGING LANDSCAPE OF PRESCRIPTION DRUG COSTS

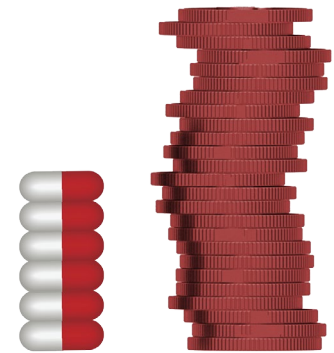
The health landscape in Canada is changing. Prior to the 1980s:

Prescription medication costs made up a relatively small proportion of health care spending. The 1980s marked a period of rapid growth for the pharmaceutical sector, owing to multiple factors such as scientific and technological advances in pharmacology; changes in population size, demographic characteristics, and health status; and shifts in patent laws and innovations in the marketing of pharmaceutical products.⁸

It is worth noting that since 2010, Canadian provinces have been working together in a group called the Pan-Canadian Pharmaceutical Alliance to lower drug costs through a bulk buying initiative. Since March 2015 there have been 63 completed joint negotiations

on brand name drugs and price reductions on 14 generic drugs, leading to \$490 million in combined savings annually.⁹ While this may seem substantial, it is only the tip of the iceberg for possible savings.

The facts surrounding the current situation are clear. Prescription and retail drugs have now become one of the top three largest contributors to health expenditures in Canada.¹⁰ Total spending on prescription drugs has nearly quadrupled since the 1990s, of which 42 per cent is financed by the public sector and 23 per cent is paid out of pocket by patients. The per capita cost of prescription medications has increased fivefold since 1984.¹¹ In 2016, Canadians will fill over 600 million prescriptions at a cost of more than \$30 billion.¹² This amount is four times more than what we spent on prescriptions 20 years ago. No other component of Canadian health care has increased in cost as quickly.¹³



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THE NEW BIG PHARMA REALITY

It seems that every other month there is a major story from south of the border about price gouging and predatory tradecraft by Big Pharma. In one example, Martin Shkreli and the drug company Turing raised the price of pyrimethamine, an old medication used to treat a parasitic infection in the brains of immune-compromised (usually HIV-infected) people from \$13.50 to \$750 a pill – an increase of over 5,000 per cent.¹⁴ In another, Health Bresch and drug company Mylan raised the price of the EpiPen auto-injector to more than \$600 for two pens right before the start of a new school year when parents were buying new EpiPens for their school-bound children.¹⁵ There is about \$1 worth of the

hormone epinephrine in each EpiPen. Through price hikes EpiPen is “becoming a \$1 billion-a-year product that clobbers its rivals and provides about 40 per cent of Mylan’s operating profits.”¹⁶ This vulgar capitalism is the industry playbook, and these companies are not just fringe actors.

The result is that the pharmaceutical sector accounts for a significant portion of government health budgets, with a fifth of the entire health care budget of Organisation for Economic Co-operation and Development (OECD) countries spent on medicines. The amount spent globally on medicines is “forecasted to grow at a compound annual rate of 4-7 per cent over

the next five years and will reach a total of \$1.3 trillion by 2018.”¹⁷

Pharmaceutical companies’ profits outpace other industries. In 2010, Big Pharma’s profits were three times higher than those of the other Fortune 500 companies combined.¹⁸ In the first quarter of 2016, more than two-thirds of the 20 biggest pharmaceutical companies used price hikes to drive large revenue growth.¹⁹

For example, sales of AbbVie’s anti-inflammatory drug humira rose 32 per cent to \$2.2 billion for the first quarter.²⁰ Over the last five years in the United States, the top 10 best selling drugs each went up in price by at least 50 per cent. Johnson & Johnson in-

creased the list price on its anti-inflammatory medication remicade, used for auto-immune disorders, by 63 per cent, while Amgen's list price on enbrel more than doubled.²¹ Cancer drug prices have also increased dramatically. A \$10,000-a-month cancer drug has become the new normal in the U.S. The average monthly amount insurers and patients paid for a new cancer drug was less than \$2,000 in the year 2000, but soared to \$11,325 in 2014.^{22,23} In Ontario alone, expenditures for cancer drugs – both intravenous and oral – was \$652 million in 2014-15, an increase of 20 per cent over the previous year.²⁴

Sofosbuvir, a hepatitis C drug manufactured by Gilead Sciences, represented an important breakthrough for patients, with cure rates of more than 90 per cent during a three month treatment. This medication could possibly eliminate hepatitis C, which is a leading infectious killer globally. It primarily affects vulnerable groups, such as people who inject drugs or have HIV/AIDS.²⁵ It has a list price in the U.S. of close to \$100,000. For Canadians, the cost related to the direct-acting antivirals (DAAs) for the treatment of hepatitis C has become a critical issue for public plans, private insurers and patients. By the second quarter of 2015, sales exceeded \$182 million in just over a two-year period.²⁶ In Canada and abroad this has meant that very few patients who would benefit from these drugs can access them, especially those in vulnerable groups who are most in need. The high price tag for DAAs has little to do with the cost of manufacturing them. Instead, the price results from what is called the drug-pricing trap.

Economists estimate that the average mark-up for patented drugs is nearly 400 per cent in the U.S.²⁷ Many other needed medications have also seen

huge price hikes in the U.S. The average price of insulin for diabetes, for example, jumped 300 per cent between 2002 and 2013. The price for heart drug isoproterenol is up 2,500 per cent, and the cost of blood pressure drug digoxin has risen 637 per cent.²⁸

Unlike most other industries, Big Pharma's ability to raise prices year after year continues unfettered.²⁹ As Doctors Without Borders has noted, "The price of Novartis's gleevec (imatinib) for leukaemia has risen three-fold in the past decade; Biogen raised the price of a treatment for multiple sclerosis an average of 16 per cent a year in the ten years since 2005, with 21 separate price hikes. On January 1, 2016, Pfizer arbitrarily raised the price on over 100 drugs in the US. Price hikes are a strategy that allows companies to maintain revenues even in the absence of successful, innovative products."³⁰ This is the reality when market forces, red in tooth and claw, decide how accessible medicines should be.

Canada is not insulated from the issues plaguing American health care. After two decades of inaction, and various approaches to managing medication costs, Canada has some of the highest drug prices in the world. No matter how you measure it, Canadians pay more for medication than they should because we lack bargaining power in a fragmented system. Take the blockbuster cholesterol drug lipitor, for example. A year's supply of the brand-name drug in Canada costs at least \$811; in New Zealand, where a public authority negotiates drug prices on behalf of the entire country, a year's supply of the brand name costs just \$15.³¹

Overall, it has been shown that the prices of generic drugs in Canada are 79 per cent higher than the median of prices found in other OECD countries. The prices of brand name drugs in

Canada are roughly 30 per cent higher than in comparable countries like the United Kingdom.³² Looking at per capita pharmaceutical expenditures, Canada's are higher than all other OECD nations, with the exception of the United States. Alternatively, if drug prices in Canada were brought down to the OECD average, the savings would be approximately \$9.6 billion annually.³³ Bringing per capita drug spending in line with spending in the United Kingdom, which performs better than the OECD average, would not only provide Canadians with better access to medications, it would also save \$14 billion annually.³⁴

Since 2000, federal government data shows that the increases in drug expenditures in Canada have outpaced increases in all other countries. Canadian drug expenditures overall increased by 184.43 per cent between 2000 and 2012, a rate higher than any other comparator country, even the United States.³⁵ In 2013, Canadians spent 1.8 per cent of our Gross Domestic Product (GDP) on pharmaceuticals. Canadians spent \$29 billion in 2015 on prescription drugs – which equals \$814 a year per Canadian, according to the Canadian Institute for Health Information.³⁶ For patented drug products, sales increased in 2015 to \$15.2 billion from \$13.8 billion in 2014, an increase of 9.5 per cent. This was the largest single increase in Canadian history of patented drug sales. In 2014, patented drug products accounted for 61.8 per cent of the total drug sales in Canada, an increase from 59.9 per cent in 2014.³⁷

Canada's generic drug prices are also exceptionally high. There is almost a 20 per cent gap between generic drug prices in Canada and those in foreign markets.³⁸ The problem rests in the

fact that instead of bargaining for a lower price:

Provinces pay an arbitrary percentage of the price charged by the company that, many years before, first marketed the drug that the generic is copying. For example, if the original drug is \$1 per pill, Ontario's Ministry of Health and Long Term Care usually aims to pay 25 per cent (so 25 cents) for the generic version. Different provinces use different percentages, but all are locked into this basic system, as are private health insurers or individual Canadians.³⁹

As a result of this, in 2010, Canadian prices were 40 per cent higher than in France, Germany, Italy, Sweden, Switzerland, the United Kingdom, the United States, the Netherlands, Spain, Australia, and New Zealand.⁴⁰ With generic prescription drug sales totaling \$5.4 billion annually, Canadians are being price gouged between \$1 billion and \$1.67 billion.⁴¹ A universal phar-

macare program would increase Canadians' bargaining power substantially and garner the best discounts through a competitive bidding process.

There is also an increase in the concentration of Big Pharma companies in Canada due to mergers and acquisitions. Four pharmaceutical companies account for more than 65 per cent of all revenues in nine out of 10 of the largest pharmaceutical subgroups.⁴² The pharmaceutical industry is concentrated in Ontario, Quebec and British Columbia, and these provinces received 94 per cent of venture capital in 2008. The poorest provinces, including Newfoundland and Labrador, New Brunswick and Prince Edward Island, received virtually no spinoff benefits from the pharmaceutical sector despite paying the same high prices as the rest of Canada.⁴³

Despite Big Pharma's record breaking profits in recent years, spending on pharmaceutical research and development (R&D) in Canada has hit historic lows. In 2014, drug companies (specifically patentees) spent 4.4 per cent

of earnings on R&D, which is the lowest amount since reporting started in 1988.⁴⁴ In 1987, pharmaceutical companies promised to increase their investment in R&D to an amount equivalent to 10 per cent of their domestic sales in return for increasing their periods of market exclusivity. This is the 12th consecutive year in a row that Canadian pharmaceutical companies have not met the 10 per cent threshold. It is a myth that subsidies and increased patent rights are needed to entice Big Pharma to conduct R&D. Research shows that public financial subsidies to attract pharmaceutical sector R&D investments are often greater than the total R&D spending of drug companies in Canada.⁴⁵ There is no economic justification for Canadians to pay an extra \$10.2 billion to generate only \$9.6 billion.⁴⁶ While drug companies like to talk about the "free market," the government grants them forms of patent rights, exclusivity for their drugs, and so on. What Big Pharma is interested in are customers, not cures.

OUR FRAGMENTED SYSTEM IS FAILING CANADIANS

Our current fragmented system means higher drug costs for everyone and huge profits for Big Pharma. Canada has a total of 19 publicly funded drug plans (10 provincial, three territorial and six federal). Eligibility, coverage and benefit payment schemes vary in each of these programs. Your postal code or socio-economic status should not dictate if you receive necessary medication, but in some provinces only people on social assistance, seniors or those suffering from certain diseases are covered, while in other provinces people are covered based on an income assessment. For example, in Ontario bunion removal and IVF services

are insured, but insulin for diabetes is not. A study tracking 600,000 patients in Ontario with diabetes found that "roughly 830 young and middle-aged patients are dying each year from want of access to something as basic as insulin – a product that we can be so truly very proud of given its discovery in Canada by Banting & Best and the award of the [Nobel] prize in 1923."⁴⁷

Of all other OECD countries, only the United States and Poland have a lower percentage of drug costs paid for by public programs (Canada is also second only to the United States in the use of private insurance).⁴⁸ It is important to note that for many of these

plans people must pay a portion of the drug costs (co-pays), which creates a proven obstacle to acquiring needed medications. The fact that a person with "\$20,000 out-of-hospital drug cancer treatment will pay nothing out-of-pocket in Nunavut, \$3,000 in British Columbia and \$20,000 in Prince Edward Island offends the principles of medicare and Canadian values."⁴⁹ There is also an issue with unequal access to medication for Canadians with private plans between provinces. With varying coverage and payment schemes between jurisdictions, beneficiaries end up paying more or less for access to essential medicines depending on where

they live, not on the basis of medical need.⁵⁰ For example, in Ontario, analysis shows that just 38 per cent of work-based private plans covered 100 per cent of the cost of drugs.⁵¹ Overall, it is estimated that individuals end up paying 22 per cent of all drug costs in Canada out of pocket.⁵² It is important to note that number excludes employees' contributions to work-based premiums as well as people who buy individual insurance plans, so the figure is likely higher.

Private plans miss the mark on their estimates of chronic disease in the workplace. For example, "59 per cent of employees have at least one chronic condition – high blood pressure, high cholesterol and depression are the most common – plan sponsors think just 32 per cent do."⁵³ For older workers, 79 per cent of employees aged 55 to 64 have at least one condition. Chronic disease is a serious issue in Canada, accounting for 67 per cent of all health care costs. For younger workers, three out of five Canadians older than age 20 have a chronic disease, while four out of five are at risk of developing one.⁵⁴

Many specialized medicines can cost \$50,000 or even \$500,000 per patient per year.⁵⁵ While the cost of maintenance drugs (for example, drugs to control blood pressure) has risen 58 per cent since 2005, biologics and specialty drugs have increased by 325 per cent in that same time.⁵⁶ Higher-cost specialty drugs are expected to account for 35 per cent of spending by 2018 (up from a prediction of 27 per cent in 2014).⁵⁷ Private drug plan providers have realized that our current system is not sustainable in the long term and are passing on more costs to beneficiaries. Recent data from the insurance industry shows that 83 per cent of private drug plan sponsors find the new drugs coming to market are

too expensive for their plans to remain sustainable, and 90 per cent of respondents agree with shifting costs on to benefit plan recipients.⁵⁸ Currently, at least 30 per cent of private plans now have maximums on drug coverage, which is leading Canadians to an American model where medication is held back from patients who require it.⁵⁹ Alternatively, a universal pharmacare plan would save the private sector \$8.2 billion annually and provide high quality, equitable coverage to everyone.⁶⁰

It is estimated that 10 million Canadians are covered by publicly funded drug plans – 9 million through provincial plans and an additional million through federal plans.⁶¹ Conversely, more than two-thirds of Canadians – close to 25 million – do not have access to a public drug plan. The large majority of Canadians – around 71 per cent – are forced to obtain drug coverage through private insurers, either through their employers or purchased individually.⁶² In a nation that prides itself on humanity, this means that 10 per cent of Canadians – around 3.5 million people – lack even basic drug coverage.⁶³ In some provinces, like British Columbia, approximately 19 per cent of the population has no drug coverage.⁶⁴ Data from Ontario suggests that:

One-quarter of people who did not have prescription medication insurance most often fell into certain groups including: people with the lowest level of education, recent immigrants, and people living in the poorest neighbourhoods.... Among those aged 12 to 64 in Ontario, 53 per cent more people living in the richest neighbourhoods had prescription medication insurance, at 85.7 per cent, compared to people living in the poorest neighbourhoods, where 56 per cent had it.⁶⁵



More than two-thirds of Canadians – close to 25 million – do not have access to a public drug plan.

Canadians working low-income jobs are cruelly one of the worst off in our system, as they generally do not have drug coverage as part of their employment, but they earn "too much" to be covered under public plans. Nearly all employees earning more than \$100,000 receive health benefits (94 per cent), compared to 32 per cent of those earning between \$10,000 and \$20,000 and 17 per cent of those earning \$10,000 or less.⁶⁶ Men are also more likely to have a benefits plan from their employer than women because women work more often in part-time jobs that do not offer health benefits.^{67,68} Only 1 in 4 part time workers have employer-provided health benefits. For workers aged 25 and under, again, only 1 in 4 have employer-provided benefits. This comes at a time when approximately 39 per cent of workers between the ages of 15 and 29 are precariously employed.⁶⁹ A recent survey found that nearly 50 per cent of respondents say they rely on each paycheck to cover their bills, with 40 per

cent admitting they spend an amount equal to all or more of their net pay each week. Twenty-five per cent stated they wouldn't be able to come up with \$2,000 if an emergency situation happened within the next month.⁷⁰ It is no surprise then that studies show that 1 in 3 Canadians with incomes under \$50,000 reported that they or someone in their house were not able to take their medication as prescribed – if at all – because of costs.⁷¹

The multi-payer Canadian system for prescription drug coverage is highly inefficient. With 24 separate companies each negotiating with large pharmaceutical companies for each individual drug price, private insurers have limited leverage with which to negotiate costs.⁷² In private plans, costly increases are passed on to beneficiaries through higher premiums, as private insurers do not negotiate drug prices with the pharmaceutical industry. The premiums for private drug insurance plans for Canadian companies continue to increase at a faster rate than drug costs. This is because most private drug plans are managed by issuance compa-

nies, which are normally compensated by a percentage of drug costs. Private insurers cover over \$10 billion in prescription drug costs in Canada.⁷³ The financial incentives for private plans do not encourage stemming the growing costs, but rather increasing them.⁷⁴ To put it another way, the goal is not cost containment or improved health outcomes, but rather the maximization of profit.⁷⁵ As a result there is growing gap between what Canadians pay in premiums and what they are receiving in benefits from private, for-profit insurance providers. For insured group plans alone:

The percentage of premiums paid as benefits dropped from 92% in 1991 to 74% in 2011. This means that Canadians were paying \$3.2 billion more in 2011 than they would have if the ratio between premiums and benefits had stayed constant since 1991. As costs increase, private plans aren't moving to contain costs, but to shift them to workers instead.⁷⁶

Overall, public plans have remained steady (if ineffective) while private insurance plans have a steep cost curve. Private insurers in Canada have overhead expenses ten times greater than the public system.⁷⁷ For example, in 2009, the cost of administration in the public health care system in Canada accounted for 3.2 per cent of total spending, while the cost of administering private insurance programs was 15.1 per cent of private insurance spending.⁷⁸ In 2011, Canadians paid \$6.8 billion more in premiums to for-profit insurance companies than they got in care, representing an overhead cost of about 23 per cent.⁷⁹ So nearly one-quarter of money paid to for-profit private plans is spent on administration and to pad profit margins. Yet private plans receive large tax subsidies that cost the federal government (and the public through taxes) over \$1.23 billion annually. Further subsidies are provided by the provinces.⁸⁰ It is estimated that \$1 billion is spent on duplicative legal, technical and administration of private drug plans.⁸¹ At the end of the day, it is patients who lose.

TRADING AWAY OUR HEALTH

The WHO's 1948 constitution outlines the right to the enjoyment of the highest attainable standard of physical and mental health as "one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."⁸² The right to health has also been enshrined in Article 25 of the 1948 Universal Declaration of Human Rights, Article 12 of the 1966 International Covenant on Economic, Social and Cultural Rights and various other international treaties.⁸³ Yet the human right to health is being undermined by a free trade system that demands endless profits.⁸⁴

In the past decade there has been a proliferation of free trade agreements whose patent rights well exceed the intellectual property (IP) provision outlined in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. These agreements, known as "TRIPS-plus," continue to advance despite the "2001 WTO Doha Declaration, which explicitly endorses the right of WTO members to protect public health and promote access to medicines for all."⁸⁵ A recent report by the United Nations Secretary-General's High Level Panel on Access to Medicines outlines that "Trade and intellectual property rules were not

developed with the goal of protecting the right to health," and noted information that pointed to "a progressive de-prioritization and erosion of human rights in the implementation of intellectual property law and policy, both under TRIPS and as a result of recent trade agreements."⁸⁶ However, the report falls short of fully condemning trade agreements with TRIPS-plus IP provisions and calling for the revision of these agreements, instead believing the false premise that the right to access medicines can be resolved within "TRIPS flexibilities" to partially tame, but not dismantle monopolies on medicine.⁸⁷ The annex to the report also

highlights that some panel members felt that the panel's recommendations were not enough and should have been bolder. These members called for TRIPS-plus measures in free trade agreements to be halted, reversed and banned, along with investor-state dispute settlement mechanisms.⁸⁸

These TRIPS-plus agreements, which are negotiated in secret, incrementally increase intellectual property and patent rights for Big Pharma, along with their enforcement (outside of national courts). The UN report outlines that these provisions:

Restrict government ability to regulate pharmaceutical prices and reimbursement mechanisms. Such provisions significantly reduce the scope of measures that national governments can use to pursue public health priorities and fulfill the right to health. Ensuring that future trade agreements do not interfere with policies that guarantee the right to health for all is essential for resolving the incoherence between trade agreements and the human right to health.^{89,90}

The current growth of drug expenditures and the erosion of the right to health will only accelerate as the Canadian government attempts to sign international trade deals that further entrench pharmaceutical patents. In a recent House of Commons committee meeting on health, the Assistant Deputy Health Minister admitted that "High prescription drug costs will rise under pending free trade agreements."⁹¹ It is estimated that the Trans-Pacific Partnership (TPP) will add more than \$800 million to prescription drug costs in Canada.⁹² Other trade deals, like the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), will increase costs by an ad-

The Pharmaceutical company – Eli Lilly – is using the ISDS provisions in NAFTA to sue Canada for \$500 million.

ditional \$850 million to \$1.65 billion annually.⁹³ Depending on whether the TPP or CETA is ratified first, drug costs are expected to rise by between 5 and 12.9 per cent starting in 2023 because of additional patent rights to the pharmaceutical industry.^{94,95}

CETA commits Canada to creating a new system of "patent term restoration," which will delay the entry of generic medicines onto the market by two years. This delay will equate to billions of dollars of profit for the brand name pharmaceutical industry at the expense of Canadians. CETA also locks Canada into longer terms of data protection/exclusivity which makes it more difficult for future Canadian governments to change limits on the length of time a drug has exclusivity in the marketplace. With CETA this could mean that the percentage of drugs having extended market exclusivity jumps from 24 per cent to at least 45 per cent.⁹⁶ This trade agreement will also allow a new right of appeal under the "patent linkage system," which could add an additional 6 to 18 months to patent life after expiring, further delaying cheaper generic drugs. The previous federal government, under former Prime Minister Stephen Harper, had pledged to compensate provinces for any additional costs. However, there was no compensation promised for individuals or private insurance plans.⁹⁷

Much of the recent discussion around the TPP and patent rights is in regards to "biologics." Biologics are a class of medical products that include a wide range of drugs that are made from biological sources. Most of the drugs we are familiar with are chemically synthesized and are made up of a relatively simple combination of molecules. Biologics are made of giant molecules that are many hundreds of times the size of conventional drug molecules (a molecule of aspirin consists of 21 atoms, whereas a biopharmaceutical molecule might contain anywhere from 2,000 to 25,000 atoms). Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances and are manufactured inside animal cells or micro-organisms such as bacteria.⁹⁸

Biologics are in the TPP because they represent big money for pharmaceutical companies. Biologics offer Big Pharma a greater chance for a "blockbuster" drug than chemically synthesized drugs. Studies suggest the global market for biologics will reach \$386.7 billion by the end of 2019.⁹⁹ Biologics provided roughly 22 per cent of the Big Pharma companies' sales in 2013. This percentage is expected to rise to 32 per cent by 2023.¹⁰⁰ The further entrenchment of biologic patents in the TPP is also an attempt to stop Subsequent Entry Biologics (SEB) from entering the highly profitable market. SEBs – called biosimilars or follow-on biologics in other countries – are in some ways "generic" versions of biologics, but biologics are more difficult to copy than conventional drugs. SEBs are typically discounted between 15 and 30 per cent from the cost of the reference drug.¹⁰¹ In comparison, prices for small-molecule generic drugs can be discounted by as much as 80 per cent relative to the patented brands they copy.¹⁰² In Canada, biologics are an increasing burden on health care

budgets. In 2010, biologics accounted for more than 14 per cent of the Canadian pharmaceutical market and cost the Canadian health care system over \$3 billion a year.¹⁰³ Biologics are expected to grow to approximately 20 per cent of the market over the next decade.¹⁰⁴ The biologic drug remicade, for example, cost Ontario \$84 million in 2012/2013, equivalent to 4.3 per cent of the Ontario Drug Benefit Plan's drug budget.¹⁰⁵ Across Canada, biologics are the largest cost driver in drug spending and three drugs alone accounted for \$1.5 billion in pharmaceutical spending in 2013.¹⁰⁶

Long before the public had heard of the TPP, the pharmaceutical industry was actively lobbying on the file. In 2009, lobbying reports in the U.S. showed that "28 organizations filed 59 lobbying reports mentioning the then far-off trade agreement. Almost half of those organizations were pharmaceutical companies or associations."¹⁰⁷ In 2015, pharmaceutical companies in the U.S. spent "50 per cent more on lobbying than the runner-up industry (insurance). That matches long-term trends with Big Pharma spending \$3.2 billion on lobbying since 1998 – almost 50 per cent more than the runner-up insurance companies."¹⁰⁸ On April 9, 2016, the Obama administration sent a document to Congress defending the TPP, describing how the TPP will make drug monopolies more common, stronger and longer, and drug prices higher – assuaging Big Pharma that their lobbying money was well spent.¹⁰⁹

While Canada's lobby reports are more general than those in the U.S., international trade was the top lobbying topic for Canada in 2015. International trade was mentioned 1,476 times in Canadian lobby communication reports that year, which is 248 more times than the second highest topic.¹¹⁰ The top three topics were international trade, indus-

While patent protected drugs only account for 10 per cent of the prescription drug market, they constitute over 72 per cent of drug spending.

try and health. All three of these topics encompass the pharmaceutical sector, depending on how the lobbyists chose to report their communications.

Big Pharma uses governments to protect its monopolies and has become dependent on trade agreements as a mechanism to expand its monopoly power. While patent protected drugs only account for 10 per cent of the prescription drug market, they constitute over 72 per cent of drug spending. The longer a drug company can extend its monopoly protection, the more profits it can make.¹¹¹ Beyond biologics provisions, these TRIPS-plus trade deals also increase secondary patents (minor changes to existing drugs) that lengthen a drug's market exclusivity. This process, known as "evergreening," delays the entry of cheaper generics onto the market, keeping the prices high. Since TRIPS agreements came about, Big Pharma adopted more complex patenting strategies since corporations can now file multiple applications for the same invention to create a set of overlapping patent rights – known as "patent thickets" that may be difficult to negotiate.¹¹² A single drug may now be protected by hundreds of patent families, which can lead to more than 1,000 patents and/or pending patent

applications across multiple countries.¹¹³ For example, in 2011 the antiretroviral medicine ritonavir, which is used along with other medications to treat HIV/AIDS, was protected by 805 patent families.¹¹⁴

There is also an inherent danger with TRIPS-plus agreements like CETA and the TPP that, in the absence of a comprehensive "carve-out" of health-related measures, there is a serious risk that pharmaceutical companies will use the investor-state dispute settlement (ISDS) mechanism to:

*Deter governments from regulating in the public interest, thereby sidestepping domestic law. Currently, the U.S. pharmaceutical company, Eli Lilly, is using the ISDS provisions in NAFTA to sue Canada for \$500 million, claiming the decision of the Canadian courts to overturn patents on two Lilly products is illegal under the trade treaty. The TPP investment text does little to curb claims like Eli Lilly's and may, in fact, make matters worse.*¹¹⁵

These trade deals will also undoubtedly create a policy chill in regards to our governments implementing better public health reforms and policy for fear of lawsuits under ISDS. Some experts in intellectual property and law believe that:

*Should Canada decide to establish a national program [for pharmacare], the policy choices will not be limited to domestic considerations. Instead, the TPP will be waiting to mandate many program requirements, including appeals and reconsideration of decisions for the benefit of pharmaceutical companies.*¹¹⁶

A BETTER MODEL, BETTER MEDICINE

While Canadians want to see the federal government fulfill its health care responsibilities, with provincial governments as working partners, concerns remain about costs. Without question, there is public aversion to the government investing new money in pharmacare, despite the huge long-term cost savings pharmacare would bring.¹¹⁷ Canadians are concerned that the cost of a universal pharmacare program will lead to increased taxes. Analysis shows that the cost to provide the program would likely be an additional \$1 billion annually.¹¹⁸ While this cost may seem high, when comparing the program's cost to the approximately \$11.4 billion that could be saved annually with the program in place, a universal pharmacare program with first dollar coverage – drug coverage being paid by a public plan without the public incurring an upfront cost – remains the strongest and most logical option. It is estimated that a universal pharmacare program could lower total spending on prescription drugs by approximately 30 per cent in Canada.¹¹⁹ If Canada had a program as strong as New Zealand's this figure would rise to \$18 billion.¹²⁰ Without competitive pricing and a system of population-wide bargaining – which we would have with pharmacare – we pay close to \$10 billion more every year for medications. Further, “since subsidies to private plans are rendered unnecessary under pharmacare, its implementation is essentially free.”¹²¹ Or to look at it another way, the Canadian government and the Department of National Defence have no problems spending \$1 billion (or more) on the Small Arms Replacement Project II; the difference is pharmacare would save lives, not take them.^{122,123}

There are competing models of pharmacare programs that policymakers regularly discuss. Many of their discus-

sions are too narrowly focused on saving money while ignoring the urgent need to improve health outcomes in the Canadian population through a fair, equitable and evidence-based pharmacare program. While fiscal considerations are, no doubt, important to the discussion, we need to acknowledge that quality health outcomes should be the compass that guides pharmacare. A universal pharmacare system with “first dollar coverage” (i.e. no co-payments, co-insurance or deductibles for individuals) is politically and fiscally sensible, and would create the highest quality health outcomes. This would also allow more than 2 million Canadians to fill prescriptions that they would not otherwise be able to afford.¹²⁴ It needs to be highlighted that, “effective prescription drug coverage policy is therefore not about just making sure everyone has some form of insurance coverage. It is about ensuring that every Canadian has effective drug coverage – coverage that provides equitable access to necessary care without financial barriers.”¹²⁵

As with any proposed expenditure and policy change of this magnitude there are large vested interests that want to see the current system maintained for their profit.¹²⁶ Other possible approaches – such as a tiered, “some drugs” program, or catastrophic coverage – are inadequate options that would still leave in place many barriers for patients because they would only address a portion of the cost and not address fundamental safety issues. For example, under catastrophic drug coverage, if patients fill their prescriptions as needed, there are deductibles included that are tantamount to a tax on the sick. It is known that “all needs-based means of paying for prescription drug costs – including deductibles, co-payments, and risk-rated premiums – are borne dispro-

Universal pharmacare could lower total spending on prescription drugs by approximately 30 per cent in Canada.

portionately by those with significant and/or ongoing health needs. This limits the financial protection provided to patients and families.”¹²⁷ Research has shown that co-pays of as little as \$2 per prescription can prevent patients from getting needed medications.¹²⁸ Further, studies show that income-based drug plans – which only cover costs above income-based deductibles – fail to promote access to needed medicines.¹²⁹

Quebec currently employs a hybrid private-public drug plan, which is often touted by corporate lobbies as the way forward for pharmacare. But this fragmented model has done little to improve fiscal barriers and contain costs. While Canada has the second-highest per capita costs for prescription drugs in the OECD, Quebec has the highest per capita cost among provinces. A recent government report noted that the system remains inequitable, inefficient and unsustainable.¹³⁰ This plan shifts the costs of the public plan onto private plans, which then pass costs onto individual beneficiaries. The private plan insurance companies receive tax subsidies and indirect subsidies, so they have little interest in containing costs. They cover all new drugs at any cost, even when lower cost alternatives are available.

CANADIANS ARE DYING BECAUSE THEY CANNOT AFFORD THEIR MEDICATION

The Canada Health Act ensures that:

*All Canadians have access to medically necessary physicians' services and hospital care – including all prescription drugs used in hospital – through universal, comprehensive, public health insurance. This system of universal health coverage in Canada does not extend to medications used in the community.*¹³¹

With 90 per cent of the pharmaceutical market in Canada in the community setting outside of our public health care system, inadequate access to necessary medication has led to adverse health outcomes and premature deaths.¹³²

The increase in the costs of necessary medication is having a negative impact on the health of the nation. In 2007, Statistics Canada found that 1 in 10 individuals did not take the medications they were prescribed because of costs.¹³³ In 2015, a survey looking at changes over the intervening eight years found that 23 per cent of households did not take their medication as prescribed because of costs.¹³⁴ Regionally, British Columbia, where the government only offers “catastrophic” drug coverage, has the highest rate of

access problems at 29 per cent, followed by Atlantic Canada at 26 per cent (where provincial plans are limited).¹³⁵

Studies report that 23 per cent of Canadian families – nearly 1 in 4 – fail to take needed medication due to costs, which has an enormous impact on health. As drug prices continue to rise, “lower income people show higher non-adherence rates, and rates of non-adherence are shown to rise as costs increase, even with fees as low as \$10.”¹³⁶ Five per cent of Canadian children and adults and 10 per cent of Canadian seniors pay over \$3,000 per year for drugs. A catastrophic drug program that only paid for these medications would still leave 19 per cent of the households without affordable access.¹³⁷

Canadians are also dying because they cannot afford their medication. A study found that in Ontario alone, “over 700 diabetic patients under the age of 65 died prematurely each year between 2002 and 2008 because of inequitable access to essential prescription drugs. That is like a plane full of Canadians crashing every year, perhaps every month, while governments refuse to take action because of concerns about costs and politics.”¹³⁸



Studies report that 23 per cent of Canadian families – nearly 1 in 4 – fail to take needed medication due to costs.

The problem of non-adherence to prescribed medications occurs in Canada at rates higher than comparable health systems in Europe and Australasia.¹³⁹ In Canada it is believed that 6.5 per cent of hospital admissions are the result of non-adherence to medications, which costs an estimated \$7 billion to \$9 billion per year.¹⁴⁰ But this says nothing about the personal trauma and health impacts these individuals experience.

A NATIONAL FORMULARY: EVIDENCE, SAFETY, APPROPRIATENESS, VALUE FOR MONEY

While containing costs and achieving long term medicare sustainability through a universal pharmacare program would have a positive impact by allowing all Canadians to get the medications they need, little is said about drug and patient safety, prescribing appropriateness, and our national regulators (Health Canada and the Patented Medicine Prices Review Board). In all

of these areas, the pervasive and toxic influence of Big Pharma has created a situation where Canadians are not receiving the quality drug coverage they deserve. Where universal pharmacare can be truly transformative is as a tool to ensure an evidence-based approach is used to achieve the best therapeutic benefits for patients.

The Canadian constitution divides the responsibility for pharmaceutical medication between the federal and provincial levels of government. Currently, the provincial governments are responsible for establishing their public formularies. A large majority of the safety and efficacy information that the provinces ultimately rely on comes from the federal government.

Moreover, much of the data comes from what Big Pharma submits to Health Canada to obtain approval for its drugs. Provinces do not have full access to the clinical trial data from drug companies because Health Canada believes the data is proprietary information and, as a result, does not release all the information needed to assess if a medication should be listed in a provincial plan. Even under Canada's Access to Information Act, Health Canada will not release the full data unless the drug company involved agrees.¹⁴¹

Universal pharmacare does not mean that every drug should be covered under the program. What is needed is a national formulary (a list of evidence-based drugs that have been approved), which is one of the most important elements currently missing in Canada's health system. This means a higher standard of evidence is needed. A new national agency is needed to provide transparency and accountability in the process of determining what drugs are covered based on appropriateness, safety, value for money, and objective evidence-based medical reviews. Other nations have similar agencies, such as the NPS MedicineWise in Australia's national strategy for quality use of medicines to ensure patients receive the best medication option.¹⁴²

This agency would provide a publicly accountable body (with representation from the public, prescribers and governments), predictable funding and transparency to increase Canada's purchasing power through the best possible formulary. Currently, Canada has no national strategy to make safe and appropriate prescription drug use part of Canadian health care culture. Patients and prescribers have limited access to unbiased information, which creates disparities and confusion. A single, evidence-based formulary would encourage the appropriate use

It is estimated that one in six hospitalizations in Canada could be prevented if prescription drugs were prescribed and used more appropriately.

of medicines while considering therapeutic value to patients.¹⁴³

Research shows that around 80 per cent of new drugs entering the market today do not have an increased therapeutic benefit to patients over existing, cheaper drugs.¹⁴⁴ At the same time, it is estimated that "private drug plans waste \$5.3 billion in reimbursements for drugs that do not provide any additional therapeutic benefits compared to existing formulations. This amount represents 56 per cent of total money spent by private drug plans."¹⁴⁵ This becomes increasingly significant when combined with the fact that Canadians will spend around \$30 billion on prescription medication in 2016.

Fifteen per cent of Canadians are aged 65 and over (classified as senior citizens).¹⁴⁶ Eighty-five per cent of seniors take at least one prescription drug and those over 80, on average, take five.¹⁴⁷ Sadly, the crisis of polypharmacy – the use of four or more medications by a patient – for Canadian seniors means that nearly 70 per cent of all seniors take five or more different drugs and almost 10 per cent take 15 or more.¹⁴⁸ Polypharmacy has been associated with functional decline, cognitive impairment, falls, negative drug interactions, adverse drug effects, prescribing cascade and many other serious health issues for seniors. At the same time, it drives up health care costs.^{149,150}

When one-third of doctors visits lead to a prescription, seniors are often not aware that the use of multiple medica-

tions increases their chances of ending up in the emergency department or being admitted to hospital. An Ontario study found that "each additional medication is associated with a 2-3 percent increase in the likelihood of hospitalization and a 3-4 percent increase in the likelihood of an ED [emergency department] visit."¹⁵¹ In 2013:

More than one in three Canadians (37 per cent) over age 65 filled at least one prescription for medicines believed to pose unnecessary risks for older adults – at a total direct cost of over \$400 million for prescriptions alone... It is estimated that one in six hospitalizations in Canada could be prevented if prescription drugs were prescribed and used more appropriately.¹⁵²

While the lack of prescribing appropriateness by physicians is not limited to seniors, they represent a clear case where we need to do more to ensure safe use and therapeutic value.

BIG PHARMA'S INFLUENCE ON PUBLIC HEALTH PROFESSIONALS

One of the distressing facts about the medical profession in Canada is that Big Pharma has a dangerous influence over physician prescribing habits. It is estimated that drug companies spend a minimum of \$60,000 per doctor per year on drug promotion.¹⁵³ Pharmaceutical sales representatives (PSRs) “visit doctors’ offices, providing wall charts and free samples, plus paying for doctors to attend conferences and give papers. It also means advertizing drugs in medical journals and to the public at large. Nothing about this process is objective.”¹⁵⁴ In 2008, 92 per cent of doctors still accepted visits from PSRs and 88 per cent saw them because they believed that they received relevant information.¹⁵⁵

A study that compared prescribing habits of primary care physicians in Montreal, Vancouver, Sacramento and Toulouse who were visited by PSRs, who are often the first information source on new drugs for doctors in Canada, found that:

*Information on health benefits was provided twice as often as information on harm, with not a single harmful effect mentioned in over half of promotions in the three North American sites... Similarly, serious harm was rarely mentioned for drugs with boxed warnings or subject to recent safety advisories... Nevertheless, physicians judged the quality of scientific information to be good or excellent in 901 (54 per cent) of promotions, and indicated readiness to prescribe 64 per cent of the time.*¹⁵⁶

The influence of Big Pharma marketing is not limited to doctors’ offices. A recent study, “comparing general medicine journals in Canada, the United

Kingdom and the United States found five times the volume of pharmaceutical advertizing in the two Canadian journals – *The Canadian Medical Association Journal* and *Canadian Family Physician* – compared with their counterparts.”^{157,158}

There is a documented “gift relationship” between physicians and Big Pharma. The ultimate goal is “not simply to promote a product. Rather, the goal is to build trust – sometimes, even friendship – so that physicians are more likely to accept what they’re told about the safety and effectiveness of not just one drug, but the next one too.”¹⁵⁹ Investigations have found in Canada that beyond PSR visits:

*Drug companies routinely host and bankroll dinners at upscale restaurants as training for family doctors. Speakers, paid by the drug company, give presentations and field questions from doctors, who get professional credits for attending the event. At more than one dinner it was found the speaker recommended a medication for certain treatments – the medication made by the same company that organized the event, paid for the wine and food and paid the doctor giving the talk.*¹⁶⁰

In Ontario alone there were more the 500 industry-sponsored events that physicians could attend to keep their licence in good standing. It was revealed roughly 70 per cent of the events listed on the College of Family Physicians of Canada’s website – the organization responsible for accrediting continuing medical education and certifying all family doctors in Canada – were put on by drug companies, sometimes indirectly through hired

No other country in the world consumes, on a per-capita basis, more prescription opioids than Canada. Approximately 410,000 Canadians reported abusing prescription drugs.

communication firms.¹⁶¹ At the same time, it has been documented that the Canadian Medical Association (CMA) took \$780,000 from Pfizer Canada to fund its new continuing medical education program (two Pfizer staff members also sat on an administrative board of the CMA during this time).¹⁶² While other professional accrediting associations – from accounting to law – say no to industry funding in this manner, the College of Family Physicians of Canada continues to take “drug-industry money to pay for its education programs despite commissioning a report on Big Pharma’s influence, which it then kept under wraps for two years.”¹⁶³ The college still “refuses to divulge an analysis of exactly how much corporate funding its educational programs receive.”¹⁶⁴ By influencing how doctors prescribe medication through the sponsorship of their education and professional development, Big Pharma has a perfect avenue to increase its sales. Not surprisingly, these programs influence prescribing habits, lead to a narrower range of topics discussed and favour the pharmaceutical sponsors’ product.¹⁶⁵

It should also be noted that doctors are not alone in taking money and gifts from Big Pharma. The choice to substitute a brand product with a generic is up to the pharmacist. However:

*Pharmacies reap the benefits of this price competition, rather than patients. Generic drug manufacturers therefore compete among themselves by trying to influence pharmacies through large rebates and gifts. Although these gifts and rebates normally go against pharmacists' code of ethics, it is estimated that 85 per cent of pharmacies accept such gifts, thus creating an institutionalized form of corruption in the pharmacy sector.*¹⁶⁶

These inducements mean that in 2009, a medium-sized pharmacy in Canada received \$240,000 a year on average in unethical revenues.¹⁶⁷ A recent federal probe into retail pharmacists found more than 1,000 failed to pay taxes for unreported benefits and incentives from generic drug companies, which is more than \$58 million in hidden income.¹⁶⁸ A universal pharmacare plan would eliminate this system of institutionalized corruption and could save at least 39 per cent on generic drugs sold in pharmacies.¹⁶⁹

The current opioid epidemic serves as a recent example of the inherent danger we face without an evidence-based national formulary, and how Big Pharma can create a dangerous public health crisis in the name of profit.^{170,171,172,173} In the late 1990s and early 2000s, Big Pharma spent hundreds of millions of dollars to 'educate' doctors on the use of opioids for treating chronic pain over the long term, and stated the risk of addiction was less than one per cent. Yet this claim had little to no scientific backing, and real world addiction rates were found to be as high as between

8 to 12 per cent.^{174,175} Purdue Pharma, the company behind oxycontin, "has a yearly promotional budget of \$14-million in Canada for its painkilling products... Virtually all those resources are targeted at the country's physicians, the gatekeepers who make or break any new medication."¹⁷⁶ In the U.S., Purdue was found guilty of misleading doctors about the addictiveness of the drugs, including using fake scientific charts.^{177,178} From 2006 to 2015, makers of opioid painkillers in the U.S. outspent the U.S. gun lobby on lobbying and campaign contribution by a ratio of eight to one.¹⁷⁹

A Purdue-funded speaker was one of the teachers in the University of Toronto's inter-faculty pain curriculum course. For years students received free copies of *Pain Management*, a textbook paid for and copyrighted by Purdue.¹⁸⁰ By 2007, companies selling opioid analgesics had given more than \$500,000 in funding to the university.¹⁸¹ It was found that "the course material contained information that aligned with the interests of these companies by minimizing opioid-related harms relative to those of other analgesics, overstating the evidence for their effectiveness, and in at least one instance, provided a potentially dangerous characterization of the potency of a commonly used opioid... Opioid prescriptions and opioid-related deaths both also rose in Ontario during the period medical students were exposed to this information in an industry-supported lecture series."¹⁸² Further, there is a parallel between the coercive marketing techniques and tactics used to promote oxycontin in the U.S. and Canada. A Newfoundland and Labrador Government Task Force on oxycontin concluded that Canadians are very much subjected to U.S. promotional material through U.S. media and are influenced by it.¹⁸³ In Nova Scotia, a class action lawsuit claimed that

the marketing strategies and tactics for oxycontin were the same as those employed in the United States.¹⁸⁴

This year, after 200 opioid-related deaths, British Columbia's chief medical officer of health declared B.C.'s first ever public health emergency.¹⁸⁵ In Alberta, deaths from fentanyl have increased by 4,500 per cent over the last five years. Fentanyl is a more potent analgesic than oxycontin, and has been around since the 1950s. The current rise in fentanyl abuse, however, correlates with the increase in opioid prescriptions like oxycontin.¹⁸⁶ In Ontario one out of eight deaths among young adults is attributable to opioids. Opioids were the third leading cause of accidental death in Ontario in 2014, and in 2013 12 per cent of Ontario high school students reported having used prescription opioids for non-medical purposes.^{187,188} No other country in the world consumes, on a per-capita basis, more prescription opioids than Canada. In 2015, doctors wrote enough prescriptions for one in every two Canadians, totalling between 19.1 million to 22 million prescriptions, depending on the source.^{189,190,191}

Overall, the federal government has recognized that "prescription drug abuse is a growing public health and safety problem in Canada, particularly among youth. In the 2012 Canadian Alcohol and Drug Use Monitoring Survey, approximately 410,000 Canadians reported abusing prescription drugs like opioid pain relievers."¹⁹² With a universal pharmacare program in place, these figures could be significantly lower. Such a program would be able to provide a coordinated national approach to the safety and appropriate prescribing of medications while removing Big Pharma's sales reps from doctors' offices.

FLAWED CLINICAL TRIALS: WE NEED BETTER EVIDENCE

More medicine does not necessarily mean better medicine. We need to “re-frame the ‘pharmacare question’ from one of simple access to one of access to what, exactly. Our gaze must turn upstream to the producers of pharmaceutical knowledge – companies that have long insisted that unpublished information about drug safety and effectiveness must be held in confidence by the regulator.”¹⁹³ There is a large body of evidence that shows that Big Pharma’s clinical trials for new medications have created an epidemic of junk science, switched outcomes, and ghost writing/authorship. It has been documented that industry-sponsored trials are more likely to report positive results than independent studies, and that researchers with financial ties to manufacturers are more likely to express opinions that are favourable to Big Pharma.^{194,195} This year, two of Canada’s major publishing houses for medical journals were bought up by an international publisher that is being sued by the U.S. government to stop it from printing what amounts to junk science for profit.¹⁹⁶ A new research project on clinical trial outcomes found that in five of the most prestigious medical journals, 58 out of 67 articles examined regarding clinical trials had “switched outcomes,” meaning that unscrupulous researchers go on fishing expeditions to prove whatever result they want.^{197,198} This manipulation of science for positive trial results undermines the safety and integrity of drug data, taints the integrity of published trials and increases the risk of exaggerated or even false-positive findings (leading to what is called the “replication crisis” in science).¹⁹⁹

Even the clinical practice guidelines for doctors, which are supposed to provide the best clinical evidence and guide doctors’ decisions, have been in-

More medicine does not necessarily mean better medicine.

fluenced by Big Pharma’s predatory influence. In Canada, the Canadian Medical Association distributes these guidelines, and a large majority of the guidelines’ authors have financial ties to Big Pharma. In a study of 350 authors from 28 of the written guidelines, 75 per cent of the documents had at least one author tied to drug companies. In 21.4 per cent of the guidelines, all authors had a financial conflict of interest with drug companies. Additionally, in 28.6 per cent of the guidelines more than half of the authors disclosed financial conflicts of interest with the manufacturers of the drugs that they recommended.²⁰⁰

Further, Big Pharma has hijacked evidence-based medicine through the process of “ghost authorship” and “ghost management” of published clinical trials to produce market-based medicine.²⁰¹ The commercialization of medical information, and the protection of that information as proprietary, has led to the privatization and commodification of science in ways that most people don’t realize.²⁰² It has become “standard practice for pharmaceutical companies to pay medical communication companies to write articles (based on industry-designed studies), for academic physicians to be paid to essentially sign off on the articles, and then for communication companies to place the articles in prestigious medical journals.”²⁰³ By controlling the process of research,

writing and publication of these articles through “ghost management,” this system allows the industry to manage the literature in ways that best serves its interests (profits). To this day, ghost authorship and management remains widespread in industry-financed medical journal literature, where those involved answer to their paymasters before ethics and evidence.²⁰⁴

In the past two decades Big Pharma companies “have developed systems that treat knowledge as a resource to be carefully developed and used to affect the opinions of researchers and practitioners. Publication of pharmaceutical company-sponsored research in medical journals, and its presentation at conferences and meetings, is now governed by ‘publication plans.’”²⁰⁵ Research and clinical trials have become marketing tools to promote the companies’ message regarding a drug through publications with positive trial results in prominent journals. It is estimated that “approximately 40 per cent of journal reports of clinical trials of new drugs (and, more anecdotally, perhaps a higher percentage of meeting presentations on clinical trials) are ghost managed through to publication.”²⁰⁶ The lack of disclosure and the industry corruption of clinical trials have resulted in physicians being misinformed, which has led to patients’ deaths. The approval of Vioxx is one such case where “patients are not merely put at risk by the way ghost management uses medical research for marketing purposes: they are actually harmed. Not only does ghost-managed research put trial participants at risk, it threatens the health of millions of patients who take drugs that might otherwise not be prescribed.”²⁰⁷

Health knowledge is largely produced by a group of Big Pharma interests

that shapes the medical discourse and prescribing habits of physicians, and ultimately has an effect on the patient. Medical science relies on the perception that it produces objective and evidence-based knowledge that is insulated from subjective analysis. Physicians relay this flawed knowledge and rely on the same biomedical authority – which patients are expected to accept passively – as free from the vested interests of drug companies. This knowledge is then further modified through the “biomediatization” of information, where health news is reported to reinforce the neoliberal ideology of consumer choice and individual patient responsibility.²⁰⁸ This ideology projects “a utopian world in which medical science and biomedical institutions serve the consumer by producing abundant information and choices, while the market serves the cause of public health,

as consumers’ responsible choices lead to healthy lifestyles.”²⁰⁹ In other words, through Big Pharma’s management of knowledge, the patient is now an individual consumer who is offered information they are told is unbiased and objective. The information presented serves the profits of the pharmaceutical industry each step of the way.

This is not to say that there is not a critical and vital place for clinical trials and medical literature. What we need is a universal pharmacare program with a new national agency to create an evidence-based national formulary that is independent from Big Pharma’s influence. The agency must ensure medicines are appropriate and generate greater benefits than harms for patients. This would include a rigorous regulatory review before the medicines come to market and monitoring after-

wards, along with public accountability. In pharmaceutical research:

*A wholesale rethink of the incentives, criteria, and processes for rewarding and carrying out drug research is needed. We need to hit the reset button so that universities are not in the business of recklessly promoting research and funding support for investigator-led and controlled drug trials, and essential groups like Cochrane Canada is restored.*²¹⁰

Beyond better medicine, universal pharmacare represents a challenge to self-interest and individualism that characterizes the current system. Only collectively can the fundamental social right to health and medicine be actualized.

ENHANCED PRICE CONTROLS

Once a drug receives a patent and is marketed in Canada, it falls under the jurisdiction of the Patented Medicine Prices Review Board (PMPRB), the quasi-judicial federal body that ensure prices are not excessive. The increased negotiating power that would come with universal pharmacare would necessitate a reframing of the PMPRB, or the creation of a new organization.

Unfortunately, the current limit on the allowable price for a particular drug is set at the median price charged for that drug in seven comparator countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the U.S.), which have some of the highest drug costs in the world.²¹¹ Using this group of countries allows Big Pharma to charge shamefully expensive prices for drugs in Canada. Four of the countries – the U.S., Switzerland, Sweden and Germany – have the most expensive brand-name prices due to

their systems, which means that every year Canada is automatically the country that ranks third or fourth highest in terms of brand name drugs. It has been estimated that moving down a few spots on this list – from fourth to seventh – Canadians could save more than \$1.4 billion or more.²¹² Further, “Canada has been losing ground to the seven countries, including the United States and France, against which the PMPRB compares drug prices to ascertain a reasonable cost. Over the past decade, patented drug prices in Canada have gone from third-lowest to third-highest among those countries,” and, “the PMPRB bears part of the blame. We are paying almost 50 per cent more.”²¹³

Setting Canadian prices based on what a selection of other countries allow makes the flawed assumption that these countries have accurately priced their medications. Further,

pharmaceutical companies tend to introduce new drugs into the American and German markets first because of the limited price controls.²¹⁴ These prices then become the benchmark for other countries. There are multiple other models that could be used or adapted for the Canadian situation, like that of New Zealand. Alternatively, the PMPRB could use countries which more closely mirror Canada, like Australia, New Zealand or Norway, for comparison. The therapeutic value of new drugs should also be re-examined periodically after their introduction to accurately determine if the costs are warranted. Lastly, the mandate of the PMPRB only extends to patented drugs, so in the case of old and off-patent orphan drugs essential to many patients – such as daraprim and trientine – where Big Pharma greatly increased their prices, there is not sufficient price control. The PMPRB’s mandate needs to be reworked.²¹⁵

In 1994 Health Canada began receiving funding through user fees from the drug industry for reviewing drug applications.

Health Canada's current mandate is to provide access to safe pharmaceuticals, but it does not look at effectiveness, costs or how pharmaceuticals compare to other products on the market. While there is a clear understanding of how enforcement decisions are made by the Food and Drug Administration (FDA) in the U.S., in Canada we do not have a full understanding of the secretive processes that are followed for approvals or enforcement.²¹⁶ This leaves the public on the outside looking in. Big Pharma, in comparison, has the advantage of working on the inside with Health Canada to game the system.

Importantly, a universal pharmacare program would be an opportunity to improve Health Canada's lack of transparency, reduce conflicts of interest, change approvals processes and address the dismal enforcement of regulations. Despite Health Canada's mandate, we continue to have unsafe prescribing and inadequate enforcement of drug safety regulations. Meanwhile, adverse drug reactions continue to be a leading cause of death in Canada.²¹⁷ The lack of "pharmacovigilance" (activities to detect, assess, understand, and prevent adverse drug effects and drug-related problems) matters significantly to health outcomes for Canadians.²¹⁸ Health Canada must begin to properly regulate Big Pharma and its marketing activities. This means ending industry self-regulation for promotion of medicines and applying more stringent rules for conflicts of

interest at Canadian teaching hospitals and universities. This would help to ensure future doctors and health professionals are trained based on the best available evidence rather than Big Pharma's commercial influences.²¹⁹ Further, "legislated disclosure of financial ties between health professionals and the pharmaceutical industry, as is now done in the U.S., would increase transparency and help to mitigate the effects of conflicts of interest of practicing health professionals."²²⁰

The health and pharmaceutical sectors share structural issues that make them susceptible to corruption and require stringent governance structures. A recent report by Transparency International highlighted that:

Public medicine procurement is even more vulnerable to corruption than contracting in other services given that medicine volumes are typically large and the contracts are usually quite lucrative... Pharmaceutical companies have the opportunity to use their influence and resources to exploit weak governance structures and divert policy and institutions away from public health objectives and towards their own profit maximising interests.²²¹

There is a long history of clientelism between Health Canada and Big Pharma. Government reports have even indicated that Health Canada serves

in an advisory capacity to Big Pharma, the very industry it is expected to regulate. Where is the accountability when the regulator also acts as an enabler to drug companies applying for licences?²²² This conflict of interest increased in 1994 when Health Canada began receiving funding through user fees from the drug industry for reviewing its drug applications (previously funding to operate our drug regulatory system came from parliamentary appropriations, i.e. tax dollars). With this new cost recovery model, in 1994, pharmaceutical companies paid \$143,800 to have a new drug application reviewed and by 2014 that amount had risen to \$322,056.²²³ As of 2015, cost recovery was expected to provide about half of the operating budget for the various drug programs of Health Canada. At other times this has been as high as 70 per cent.^{224,225} Because of this outrageous conflict of interest, it is no surprise that numerous Health Canada documents prioritize Big Pharma's profit-based goals to get its drugs to market quickly over health protection and safety. Beyond more hasty reviews, Health Canada created two mechanisms to get drugs to market even faster: priority approvals and the Notice of Compliance with conditions (NOC/c). For Health Canada, innovation means meeting Big Pharma's agenda of more drugs on the market as fast as possible. Further, there is no requirement in the Food and Drug Regulations that sets a standard as to how effective a new drug has to be.

The threshold for drug approval remains low in Canada as "a drug does not have to be better than an existing drug to be approved, but only better than a placebo. Health Canada therefore approves new brand name drugs that are more expensive than existing drugs, but provide no additional therapeutic value, or even less therapeutic

tic value than drugs already on the market.”²²⁶ Many of these new drugs approved are known as ‘me-too’ or ‘follow on’ drugs. They feature a small variation to the original drug, but can create a large profit. For example, the heartburn and ulcer medication nexium is a derivative of the older drug prilosec, but the reformulation and repackaging allowed the manufacturer, AstraZeneca PLC, to prolong its patent and subsequently its profits.²²⁷ Yet less is known about the safety of these drugs as they have only been subject to clinical trials in controlled environments, whereas earlier drugs have safety data from previous usage in the general public. At least 85 per cent of the drugs approved by Health Canada are these me-too drugs, which are more expensive and of questionable therapeutic advantage.²²⁸ In British Columbia it was documented that me-too drugs accounted for 41 per cent of spending in 1996. This jumped to nearly two-thirds of spending in 2003. This is close to 80 per cent of the increased spending.²²⁹

More medicine does not necessarily mean better medicine. There is a disturbing trend where Health Canada has been speeding up drug approvals without properly assessing patients’ safety. Health Canada has also been weakening drug safety regulations.²³⁰ The Auditor General reports that Health Canada already fails to give timely safety warnings, disclose information on drug trials or address conflicts of interest.²³¹ As Health Canada continues to take large sums of money from Big Pharma, there has been an increasing deregulation of clinical trials, drug approvals, safety, promotion and post-market monitoring. More and more trials are now managed by contract research organizations (CROs), which are for-profit organizations. The CROs are linked to a rise in ghost authorship, poor transparency, design bias, non-disclo-

sure agreements and little government oversight. It is clear the CROs are interested more in profit than public safety. When 345 new active substances approved between 1997 and 2012 were evaluated for their therapeutic benefits by independent organizations, “91 were given priority reviews. Only 52 of them, however, were judged to be therapeutically innovative.”²³² It has been found that “drugs having received a priority review in Canada have a 34 per cent chance of acquiring a serious safety warning compared to just under 20 per cent for those given standard reviews.”²³³

For decades Health Canada has kept important safety information confidential at the behest of drug manufacturers. Post-market surveillance of medications (i.e. monitoring new drugs once they begin to be sold to the public) remains inadequate despite the recent federal bill titled *Protecting Canadians from Unsafe Drugs Act*, better known as Vanessa’s Law.²³⁴ It has been outlined that:

*Although Vanessa’s Law created new transparency powers, it also legitimated Health Canada’s long-standing practice of treating drug safety and effectiveness information as proprietary. The definition of ‘confidential business information’ in the legislation can accommodate drug safety and effectiveness data provided that the data is not publicly available.*²³⁵

It seems that Health Canada is continuing, for all intents and purposes, its long-held policy of keeping important safety and effectiveness information confidential at the request of the pharmaceutical industry.

It took one doctor trying to ensure the safety of his pregnant patients approx-

imately three and a half years to get information about diclectin, a drug taken for morning sickness. What he received after years of relentlessly pursuing Health Canada was 359 pages of documents with 212 pages entirely redacted, including the sections on “Adverse Events.” After the ordeal the doctor highlighted, “This shows that it is practically impossible for a doctor to get information from Health Canada – even for a drug that is commonly prescribed to pregnant women.”²³⁶ In many cases, disclosing this “proprietary” information would prevent major harm and save lives. In the case of vioxx, which was “approved in 1999 for treating arthritis, it was withdrawn from markets in 2004 after thousands are estimated to have suffered cardiac arrest and death. Regulatory officials knew of this risk but kept it secret on the grounds it was company property.”^{237,238} Health Canada’s lack of transparency regarding the effectiveness and safety of drugs leaves both patients and physicians misinformed.²³⁹ Canadians have “a right to know how safe and effective – or unsafe and ineffective – their medicines are. Anything less will come at a great cost to patient safety and public health.”²⁴⁰

It is not hyperbole to say that in many cases Health Canada serves as a detriment to the well-being of the Canadian public. There is an obvious juxtaposition between the goals of public health and the profit seeking motives of Big Pharma. Universal pharmacare would provide an opportunity to revamp the ethically bankrupt policies of accepting uses fees from Big Pharma and an occasion to require stronger clinical trials to ensure increased safety while judging the therapeutic value of drugs. This would include releasing all safety data whether a new drug is approved or denied. In the case of a safety advisory or withdrawal occurring, Health Canada must stop negotiating wording with

companies and ensure the information is released as expediently as possible. Further, Health Canada should attach robust and enforceable post-market monitoring conditions to drug companies' product licences. This is especially important for informing formulary evaluations of those interventions as real world evidence about the benefits and harms of a drug accumulates.²⁴¹ With these changes must come a sincere policy change to increase transparency.

Lastly, there is no jurisdiction in Canada that has the population size or technical capacity to effectively monitor all of the potentially important indicators

of drug safety and effectiveness for patients.²⁴² A universal pharmacare program would have the capacity to develop a pan-Canadian drug safety surveillance program. The monitoring of prescribing practices, medicine safety and health outcomes are currently inadequate. With the management of medicines in isolated systems and plans, we lag behind other countries in the safe and appropriate use of medicines. For example, "fewer than one in three doctors in Canada use electronic prescribing tools to help identify problems with drug doses or interactions. In contrast, about 9 in 10 doctors use such systems in New Zealand and the United Kingdom – countries where

public coverage of pharmaceuticals and health care are integrated."²⁴³ With improved monitoring, surveillance and prescribing systems, it is estimated that universal pharmacare could "realistically reduce by 50 per cent the existing problems of medicine underuse, overuse, and misuse. This would dramatically improve patient health while reducing costs of medical and hospital care by up to \$5 billion per year."²⁴⁴ Health Canada would play a significant role in providing objective safety and prescribing information to doctors, health care professionals, and the public for drugs used under a national formulary.

CANADIANS CALL FOR PHARMACARE

The health of Canadians "is not a gift; at its best, it can be a fragile accomplishment attained only through collective action."²⁴⁵ Doubling down on our current patchwork system will only increase the influence of Big Pharma and the inequities Canadians currently face. While vested interests say universal pharmacare is not affordable, this claim is bankrupt as evidence shows it is the key to affordability. The general public in Canada may not all be aware of statistical and technical data outlined above, but Canadians know medications should be a basic human right and not a commodity. The demand for pharmacare remains exceptionally high across Canada. A major poll in 2015 found that a striking 91 per cent of Canadians support a universal pharmacare plan.²⁴⁶

The Federation of Canadian Municipalities, representing 90 per cent of Canada's municipal population, has endorsed a motion to "call on the federal government to work with the provinces and territories to develop and implement a National Pharmacare

**91 per cent of
Canadians support a
universal pharmacare
plan.**



program."²⁴⁷ Even business groups like the B.C. Chamber of Commerce have recommended that the provincial and federal governments work together to create a universal pharmaceutical program.²⁴⁸ Recent data shows that 90 per cent of businesses in Canada felt generally positive towards the idea of a public pharmacare program.²⁴⁹

Prescription drugs generally represent the largest portion of the cost for employer-provided benefits and are a contentious bargaining issue.²⁵⁰ Universal pharmacare would bring down labour costs in Canada as drug benefits would no longer be a part of labour ne-

gotiations. This would save businesses money, while improving the competitiveness of Canada's labour market. As a result of our medicare, Canada has already been an attractive source for investment from our largest trading partner, the U.S., as our universal single-payer system offers a competitive advantage for business. Medicare already provides Canadian employers with a competitive advantage equal to approximately \$4 an hour. Since pharmaceuticals are the second largest component of health care spending in Canada, a universal, public pharmacare program would add considerably to this advantage.²⁵¹

No other policy change and program can have the same kind of positive impact on the well-being of Canadians while saving as much as \$11 billion annually.

While the Liberals' 2015 election platform and the mandate letter to the Health Minister both make commitments to making prescription drugs more affordable in Canada, there are questions regarding the political will to implement a pharmacare program.^{252,253} Further, while affordability is an important factor, improving health outcomes and equity should also be a key feature of the mandate. Governments in Canada should strive for better outcomes for their citizens. In March 2016, the multi-party Standing Committee on Health of the House of Commons began a study on the development of a national pharmacare program.²⁵⁴ Many other countries have shown that they can achieve better outcomes with a universal pharmacare plan. Adding additional momentum, at the biennial Liberal Party of Canada convention in May of 2016, delegates approved a motion to support a "national-universal pharmacare program as one of its policy priorities," and "implement a national pharmacare plan in place within its first mandate."²⁵⁵

Unfortunately, like previous Liberal health ministers before her, Minister Jane Philpott indicated that pharmacare is not part of her mandate.²⁵⁶ She fears it would be too costly, stating, "It sounds like it might be expensive and that's one of the reasons we're not in the position where we're about to implement pharmacare."²⁵⁷ While the health minister is no doubt aware of the inaccuracies in her statement – and that Canadians will end up paying

for this one way or another – there seems to be a lack of political will and courage within the government.

There has never been a better political moment for pharmacare. There is overlapping interest between provincial and territorial governments, and multiple examples of other comparable countries that show that better health outcomes and savings can be achieved through universal pharmacare. Many of the current governing parties in Canada – including parties governing in Ontario, Quebec, and federally – are "Liberal parties that share a common base of political support. This is an exceptionally rare alignment of Canadian governments – arguably one not seen during the history of pharmacare discussions in Canada."²⁵⁸ While there are many complexities that need to be unpacked, never has there been an alignment like we have today. For pharmacare to become a reality in our federation, Quebec and Ontario need to be on-side. Ontario is currently taking the lead on this issue. Quebec is "also interested in improving their system and might be willing to work with a federal government on improvements, if conditions are right."²⁵⁹ Further, the current Health Accord negotiations offer a pragmatic opportunity and realistic tool to implement pharmacare. The Health Accord is a logical place to finally start the process of implementing universal pharmacare with fixed commitments. An issue as significant as the health of Canadians

is too important to be left to the whims of election cycles.

No other policy change and program can have the same kind of positive impact on the well-being of Canadians while saving as much as \$11 billion annually. The evidence shows that our current system is untenable in the long term and that it cannot control rising drug costs, but we have other viable options. Now, more than ever, we need good pharma, not Big Pharma. Canadians are at the breaking point and "cannot continue to quietly pay these outrageous prices for drugs while we cut spending in other areas of health care." So will our government "take up the challenges represented by our aging population, spiraling drug costs and an increasingly fragmented system and commit to pharmacare, or will they stay on the current path, fiddling around the edges, without confronting the real issues?"²⁶⁰

The missing ingredient in this is federal leadership and a desire for real change from the government. For too many generations our government has acquiesced to the interests of Big Pharma while Canadians have suffered the consequences. It is only political apathy that is holding us back from fair, equal and universal access to necessary medications for all Canadians. Now is the time to commit to a more compassionate society where all Canadians have the right to good health and better medicine. Now is the time for universal pharmacare.

ENDNOTES

1. "The Selection of Essential Medicines." WHO Policy Perspectives on Medicines, 004. World Health Organization. June 2002.
2. "Medicare Should Cover Prescription Drugs: Editorial." *Toronto Star*. 9 June 2015.
3. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, and J. Lexchin. "Pharmacare 2020: The Future of Drug Coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
4. Gagnon, Marc-André. "The Economic Case for Universal Pharmacare: Costs and Benefits of Publicly Funded Drug Coverage for all Canadians." Canadian Centre for Policy Alternatives. 13 September 2010.
5. Morgan S.G., M.A. Gagnon, B. Mintzes, and J. Lexchin. "A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy in Canada." *Healthcare Policy*, 12(1): May 2016.
6. Anis, A.H. "Pharmaceutical Policies in Canada: Another Example of Federal-Provincial Discord." *Canadian Medical Association Journal*. 162(4): 2000.
7. Boothe, Katherine. "Ideas and the Pace of Change: National Pharmaceutical Insurance in Canada, Australia, and the United Kingdom." University of Toronto Press. 2015.
8. Salehi, Leila. "National Pharmacare Time to Move Forward." *Canadian Family Physician*, 62(7): July 2016.
9. White, Julie. "A National Public Drug Plan for All." Canadian Health Coalition. May 2016.
10. "National health expenditure trends, 1975-2014." Canadian Institute for Health Information. 2014.
11. Salehi, Leila. "National Pharmacare Time to Move Forward." *Canadian Family Physician*, 62(7): July 2016.
12. "Pharmacy in Canada." Canadian Pharmacists Association. February 2016.
13. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, and J. Lexchin. "Pharmacare 2020: The Future of Drug Coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
14. Pollack, Andrew. "Drug Goes From \$13.50 a Tablet to \$750, Overnight." *The New York Times*. 20 September 2015.
15. Rosenthal, Elisabeth. "The Lesson of EpiPens: Why Drug Prices Spike, Again and Again." *The New York Times*. 3 September 2016.
16. Koons, C. and R. Langreth. "How Marketing Turned the EpiPen Into a Billion-Dollar Business." *Bloomberg Business Week*. 23 September 2016.
17. "Corruption in the Pharmaceutical Sector: Diagnosing the Challenges." Transparency International. June, 2016.
18. Gøtzsche, Peter. *Deadly Medicines and Organised Crime: How Big Pharma has Corrupted Healthcare*. Radcliffe Publishing: 2013.
19. Walker, Joseph. "Drugmakers' Pricing Power Remains Strong." *Wall Street Journal*. 14 July 2016.
20. Ibid.
21. Humer, Caroline. "Exclusive: Makers Took Big Price Increases on Widely Used U.S. Drugs." *Reuters*. 5 April 2016.
22. Johnson, Carolyn Y. "The contradictory reasons cancer-drug prices are going up." *The Washington Post*. 2 May 2016
23. Dusetzina, Stacie B., "Drug Pricing Trends for Orally Administered Anticancer Medications Reimbursed by Commercial Health Plans, 2000-2014." *JAMA Oncology*, 2(7): July 2016.
24. "Working Together for Change: Ontario Public Drug Programs Annual Report 2014-2015." Government of Ontario. 31 March 2015.
25. Roy, Victor and Lawrence King. "Betting on hepatitis C: how financial speculation in drug development influences access to medicines." *BMJ*, 354:i3718: 2016.
26. Patented Medicine Prices Review Board. "Cost Pressure of the New Hepatitis C Drugs in Canada." Government of Canada. 13 April 2016.
27. Brennan, H., A. Kapczynski, C.H. Monahan, and Z. Rizvi. "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health." *Yale Journal of Law & Technology* (275): 2016.
28. Kesselheim A, J. Avorn, and A. Sarpatwari. "The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform." *Journal of the American Medical Association*, 316(8): 2016.
29. Walker, Joseph. "Drugmakers' Pricing Power Remains Strong." *Wall Street Journal*. 14 July 2016.
30. "Lives on the Edge: Time to Align Medical Research and Development with People's Health Needs." Médecins Sans Frontières. May 2016.
31. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, J.R. Daw, and J. Lexchin. "Pharmacare 2020: The future of drug coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
32. Ibid.
33. "CLHIA Report on Prescription Drug Policy: Ensuring the Accessibility, Affordability and Sustainability of Prescription Drugs in Canada." Canadian Life and Health Insurance Association Inc. 2013.
34. Dutt, Monika. "Affordable Access to Medicines A Prescription for Canada." Canadian Centre for Policy Alternatives. December 2014.

35. "Annual Report 2014." Patented Medicine Price Review Board. 16 November 2015.
36. "Evidence Wednesday, April 13, 2016." House of Commons Standing Committee on Health. 13 April 2016.
37. "Annual Report 2014." Patented Medicine Price Review Board. 16 November 2015.
38. "Generics360 – Generic Drugs in Canada." Patented Medicine Price Review Board. February 2016.
39. Attaran, Amir. "Canada Is Needlessly Bleeding Money on Generic Drugs." *Toronto Star*. 17 February 2016.
40. "Canadian Drug Price Gouging for Generics Called 'Hard to Celebrate'." *CBC News*. 9 February 2016.
41. Attaran, Ami. "Canada Is Needlessly Bleeding Money on Generic Drugs." *Toronto Star*. 17 February 2016.
42. "Annual Report 2014." Patented Medicine Price Review Board. 16 November 2015.
43. Gagnon, Marc-André. "The Economic Case for Universal Pharmacare: Costs and Benefits of Publicly Funded Drug Coverage for all Canadians." Canadian Centre for Policy Alternatives. 13 September 2010.
44. "Annual Report 2014." Patented Medicine Price Review Board. 16 November 2015.
45. Hebert, Guillaume. "The pharmaceutical industry in Québec: time for assessment." Canadian Centre for Policy Alternative. 13 June, 2012.
46. Gagnon, Marc-André. "The Economic Case for Universal Pharmacare: Costs and Benefits of Publicly Funded Drug Coverage for all Canadians." Canadian Centre for Policy Alternatives. 13 September 2010.
47. Flood, Colleen. "Remarks to the House of Commons' Standing Committee on Health: Development of a National Pharmacare Program." University of Ottawa Centre for Health Law, Policy & Ethics. 26 September 2016.
48. Church, Elizabeth. "Canada among Top Pharmaceutical Spenders on OECD List." *The Globe and Mail*. 4 November 2015.
49. Picard, André. "Action, not excuses, on drug coverage." *The Globe and Mail*. 6 April 2011.
50. Demers, V., M. Melo, C. Jackevicius, J. Cox, D. Kalavrouziotis, S. Rinfret, et. al. "Comparison of provincial prescription drug plans and the impact on patients' annual drug expenditures." *Canadian Medical Association Journal*, 178(4): 2008.
51. Mercer Canada Limited. "Cost Trends in Health Benefits for Ontario Businesses: Analysis for Discussion. Commissioned by the Ontario Chamber of Commerce for Release at the Ontario Economic Summit." 17 November 2011.
52. "Expenditure on Drugs by Type, by Source of Finance, Canada, 1985-2015." Canadian Institute for Health Information. 2013.
53. "Report Card: Evaluating workplace supports for health management." 2016 Sanofi Canada Healthcare Survey. 13 June 2016.
54. Harris, Lauren. "Healthy Outcomes: Getting a better handle on chronic disease." Benefits Canada. 1 September 2016.
55. Morgan, Steve and Danielle Martin. "Morgan & Martin: Pharmacare: It's Good for Business." *National Post*. 15 April 2015.
56. Butler, Don. "Skyrocketing Costs Make Canada's Private Drug Plans Unsustainable, Insurance Exec Tells Pharmacare Panel." *National Post*. 27 May 2013.
57. Welds, Karen. "Drug plan trends report: How drug plans are addressing skyrocketing costs." Benefits Canada. 18 March 2016.
58. Gang, Yaelle. "Employers urged to take more active role in controlling drug costs." Benefits Canada. 15 June 2016.
59. Welds, Karen. "Drug plan trends report: How drug plans are addressing skyrocketing costs." Benefits Canada. 18 March 2016.
60. Morgan, Steve and Danielle Martin. "Morgan & Martin: Pharmacare: It's Good for Business." *National Post*. 15 April 2015.
61. "Pan Canadian Drugs Negotiations Report." Pan-Canadian Pharmaceutical Alliance. 22 March 22, 2014.
62. Ibid.
63. White, Julie. "A National Public Drug Plan For All." Canadian Health Coalition. May 2016.
64. "Prescription drug access and affordability an issue for nearly a quarter of all Canadian households." Angus Reid Institute. 15 July 2015.
65. "Measuring Up A yearly report on how Ontario's health system is performing." Government of Ontario. October 2016.
66. Canadian Union of Public Employees. "Submission to the House of Commons Standing Committee on Health Development of a National Pharmacare Program." September 2016.
67. Snyder, Jo. "PharmaCare: Decreasing disparity between rich and poor." Wellesley Institute. 29 July 2015.
68. Barnes, Steve and Laure Anderson. "Low Earnings, Unfilled Prescriptions: Employer-Provided Health Benefit Coverage in Canada." Wellesley Institute. 2015.
69. Foster, Melisa. "Pharmacare: Why Millennials Should Pay Attention." *Healthy Debate*. 3 August 2016.
70. "Canadians living pay cheque to pay cheque, challenged by debt and economy, payroll survey finds." Canadian Payroll Association. 7 September 2016.
71. "Prescription drug access and affordability an issue for nearly a quarter of all Canadian households." Angus Reid Institute. 15 July 2015.

72. Canadian Union of Public Employees. "Submission to the House of Commons Standing Committee on Health Development of a National Pharmacare Program." September 2016.
73. Morgan S. and K. Booth. "Universal prescription drug coverage in Canada: Long-promised yet undelivered." *Healthcare Management Forum*, 1(8), October 2016.
74. Silversides, Ann. "Ontario's law curbing the cost of generic drugs spark changes." *Canadian Medical Association Journal*, 181 (3–4), 4 August 2009.
75. Law M.R., J. Kratzer, and I.A. Dhalla. "The increasing inefficiency of private health insurance in Canada." *Canadian Medical Association Journal*, 186(12): March 2014.
76. Canadian Union of Public Employees. "Submission to the House of Commons Standing Committee on Health Development of a National Pharmacare Program." September 2016.
77. Ibid.
78. "National Health Expenditure Trends, 1975 to 2012." Canadian Institute for Health Information, 2012.
79. Law, M.R., J. Kratzer, and I.A. Dhalla. "The increasing inefficiency of private health insurance in Canada." *Canadian Medical Association Journal*, 186(12): March 2014.
80. Gagnon, Marc-André. "Pharmacare and Federal Drug Expenditures: A Prescription for Change." How Ottawa Spends, 2013.
81. Gagnon, Marc-André. "The Economic Case for Universal Pharmacare: Costs and Benefits of Publicly Funded Drug Coverage for all Canadians." Canadian Centre for Policy Alternatives. 13 September 2010.
82. "Constitution of the World Health Organization." World Health Organization. 7 April 1948.
83. United Nations Secretary-General's High Level Panel on Access to Medicines. "Promoting Innovation and Access to Health Technologies." United Nations. 14 September 2016.
84. Chen, Michelle. "Free-Trade Deals Are Making It Much Harder to Fight AIDS: The Trans-Pacific Partnership and its ilk protect profits at the expense of prevention." *The Nation*. 19 September 2016.
85. Forman, Lisa and Gillian MacNaughton. "Lessons learned: a framework methodology for human rights impact assessment of intellectual property protections in trade agreements." *Impact Assessment and Project Appraisal*, 34(1), 25 March 2016.
86. United Nations Secretary-General's High Level Panel on Access to Medicines. "Promoting Innovation and Access to Health Technologies." United Nations. 14 September, 2016.
87. "Health Gap Statement on the Final Report of the UN Secretary-General's High Level Panel on Access to Medicines." Health Gap Global Access Project. 14 September 2016.
88. United Nations Secretary-General's High Level Panel on Access to Medicines. "Promoting Innovation and Access to Health Technologies." United Nations. 14 September, 2016.
89. Ibid.
90. Baker, Brook and Katrina Geddes. "Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines - Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement." *Journal of Intellectual Property Law*, 23(1): October 2015.
91. "Gov't sees drug costs rising." *Blacklocks Reporter*. 19 Apr. 2016.
92. Yussuff, Hasssan. "Letter to Chrystia Freeland Minister of International Trade." Canadian Labour Congress. 27 January 2016.
93. Beltrame, Julian. "Trade Deal to Increase Cost of Prescription Drugs by up to \$1.65-billion, Report Warns." *The Globe and Mail*. 30 October 2013.
94. Lexchin, Joel. "Involuntary Medication: The Possible Effects of the Trans-Pacific Partnership on the Cost and Regulation of Medicine in Canada." Canadian Centre for Policy Alternative. 3 February 2016.
95. Sinclair, Scott. "Major Complications: The TPP and Canadian Health Care." Canadian Centre for Policy Alternative. 3 February 2016.
96. Hollis, Aidan and Paul Grootendorst. "Drug Market Exclusivity in the EU and Canada: Problems with Norton Rose's Comparative Analysis." Canadian Generic Pharmaceutical Association. January 2012.
97. Beltrame, Julian. "Trade deal to increase cost of prescription drugs by up to \$1.65-billion, report warns." *The Globe and Mail*. 30 October 2013.
98. Otto, Ralf, Alberto Santagostino, and Ulf Schrader. "Rapid growth in biopharma: Challenges and opportunities," McKinsey and Company. December 2014.
99. Weeks, Carly. "Prescription-drug Spending Holds Steady, but Dollars Spent on Biologics Escalating Quickly: Report." *The Globe and Mail*. 28 May 2015.
100. "Going Large." *The Economist*. 3 January 2015.
101. Morgan, Steve and Matthew Renwick. "Is Canada Paying Too Much for Generic Biological Drugs?" Healthy Debate. 11 March 2015.
102. Law, Michael and Jillian Kratzer. "The road to competitive generic drug prices in Canada." *Canadian Medical Association Journal*, 185(13): 17 September 2013.
103. Canadian Agency for Drugs and Technologies in Health. "Subsequent Entry Biologics – Emerging Trends in Regulatory and Health Technology Assessment Frameworks." *Environmental Scan*, Issue 43: 9 January 2014.

104. "Regulatory Landscape: Subsequent Entry Biologics." The Canadian Generic Pharmaceutical Association. 10 May 2015.
105. Ontario Ministry of Health and Long Term Care. "2012/13 Report Card for the Ontario Drug Benefit Program." Government of Ontario.
106. Innovation, Science and Economic Development Canada. "Pharmaceutical Industry Profile." Government of Canada. 19 January 2015.
107. Drutman, Lee. "How Big Pharma (and others) began lobbying on the Trans-Pacific Partnership before you ever heard of it." Sunlight Foundation. 13 March 2014.
108. Weissman, Robert. "Rx for Outrageous Drug Prices: Heal Our Democracy." *The Huffington Post*. 6 April 2016.
109. Love, James. "Obama Administration memo: 'Background on TPP Biopharma Provisions.' describes how TPP will raise drug prices." Knowledge Ecology International. 12 April 2016.
110. Vigliotti, Marco. "Hot topics: International trade file tops lobbying in 2015, as groups jockey for influence on TPP, CETA." Lobby Monitor. 5 February 2016.
111. "Game of Patents – How the US Government and Big Pharma Protect Pharmaceutical Profits." The Institute for Health and Socio-Economic Policy. 30 September 2016.
112. United Nations Secretary-General's High Level Panel on Access to Medicines. "Promoting Innovation and Access to Health Technologies." United Nations. 14 September 2016.
113. European Commission Competition DG. "Pharmaceutical Sector Inquiry Final Report." 8 July 2009.
114. Landon, I.P. "Patent Landscape Report on Ritonavir." World Intellectual Property Organization. 28 October 2011.
115. Lexchin, Joel and Deborah Gleeson. "TPP and pharmaceutical regulation in Canada and Australia." *International Journal of Health Services*, 11 August 2016.
116. Geist, Michael. "The Trouble With the TPP, Day 33: Setting the Rules for a Future Pharmacare Program." 18 February 2016.
117. Holliday, Ian. "Most Canadians want government to expand the services it provides, but they don't want to pay for it." Angus Reid Institute. 22 August 2016.
118. Morgan, Steve and Danielle Martin. "Morgan & Martin: Pharmacare: It's Good for Business." *National Post*. 15 April 2015.
119. Morgan, S. and K. Booth. "Universal prescription drug coverage in Canada: Long-promised yet undelivered." *Healthcare Management Forum*, 1(8), October 2016.
120. Morgan, Steve. "A better prescription: the evidence and politics of pharmaceutical policy in Canada." Grand Rounds, UBC SSPH Seminar Series. 23 September 2016.
121. Dutt, Monika. "Rx For Drug Benefits." *The Globe and Mail*. 28 July 2015.
122. Harris, Paul, et. al. "Canadian Small Arms Demonstration Project." Defence Research and Development Canada. May 2008.
123. "The evolution of the smart gun." Defence Research and Development Canada. 9 February 2015.
124. Morgan, S.G., J.R. Daw, and M.R. Law. "Rethinking Pharmacare in Canada." C.D. Howe Institute, Commentary No. 384. June 2013.
125. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, J.R. Daw, and J. Lexchin. "Pharmacare 2020: The future of drug coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
126. Foster, Melisa, and Steve Long. "Pharmacare: Lost in Translation." Global Public Affairs. July 2016.
127. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, J.R. Daw, and J. Lexchin. "Pharmacare 2020: The future of drug coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
128. Goldman, Dana, et. al. "Prescription drug cost sharing: Associations with medication and medical utilization and spending and health." *Journal of the American Medical Association*, 298(1): 2007.
129. Morgan, S.G., J.R. Daw, and M.R. Law. "Are Income-Based Public Drug Benefit Programs Fit for an Aging Population?." Institute for Research on Public Policy. 3 December 2014.
130. Gagnon, Marc-André. "Bring in Pharmacare – but not inefficient Quebec model." Policy Options. 2 July 2015.
131. Morgan, S.G., M.A. Gagnon, B. Mintzes, and J. Lexchin. "A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy in Canada." *Healthcare Policy*, 12(1) May 2016.
132. Ibid.
133. Statistics Canada. "Canadian Community Health Survey - Annual Component (CCHS)." Government of Canada. 17 June 2008.
134. "Prescription Drug Access and Affordability an Issue for Nearly a Quarter of All Canadian Households." Angus Reid Institute. 15 July 2015.
135. Ibid.
136. Dutt, Monika. "Parliamentary Submission to HESA on Pharmacare." Canadian Doctors for Medicare. 6 June 2016.
137. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, J.R. Daw, and J. Lexchin. "Pharmacare 2020: The future of drug coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
138. Canadian Federation of Nurses Unions. "Summary of CFNU's Parliamentary Breakfast Filling the Prescription: The case for pharmacare now." 31 May 2016.

139. Morgan S.G., M.A. Gagnon, B. Mintzes, and J. Lexchin. "A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy in Canada." *Healthcare Policy*, 12(1) May 2016.
140. Dutt, Monika. "Parliamentary Submission to HESA on Pharmacare." Canadian Doctors for Medicare. 6 June 2016.
141. Lexchin J, M. Wiktorowicz, and K. Moscou. "Provincial Drug Plan Officials' Views of the Canadian Drug Safety System." *Journal of Health Politics, Policy and Law*, 38(3): 2013.
142. Morgan S.G., M.A. Gagnon, B. Mintzes, and J. Lexchin. "A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy in Canada." *Healthcare Policy*, 12(1) May 2016.
143. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, J.R. Daw, and J. Lexchin. "Pharmacare 2020: The future of drug coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
144. Gagnon, Marc-André, "Who's afraid of universal pharmacare?." Evidence Network, June 2013.
145. Gagnon, Marc-André. "Marc-André Gagnon: The Case for National Pharmacare." *National Post*. 10 July 2013.
146. Statistics Canada. "Canada's population estimates: Age and sex, July 1, 2015." Government of Canada. 29 September 2015.
147. Simpson, Jeffrey. "Why Not a National Drug Plan for Seniors Similar to CPP?." *The Globe and Mail*. 5 March 2016.
148. Cassels, Alan. "Prescription Drug Use among Seniors Far Too High." CBC. 22 May 2016.
149. Maher Jr., R.M., J.T. Hanlton, and E.R. Hajjar. "Clinical Consequences of Polypharmacy in Elderly." *Expert Opinion Drug Safety*, 13(1): January 2014.
150. Samoy, L.J., P.J. Zed, K. Wilbur, R.M. Balen, R.B. Abu-Laban, and M. Roberts. "Drug-Related Hospitalizations in a Tertiary Care Internal Medicine Service of a Canadian Hospital: A Prospective Study." *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*, 26(11): November 2006.
151. Allin, S., D. Rudoler, and A. Laporte. "Does Increased Medication Use among Seniors Increase Risk of Hospitalization and Emergency Department Visits?." Health Services Research. 27 September 2016.
152. Morgan S.G., M.A. Gagnon, B. Mintzes, and J. Lexchin. "A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy in Canada." *Healthcare Policy*, 12(1) May 2016.
153. Gagnon, Marc-André and Joel Lexchin. "The cost of pushing pills: a new estimate of pharmaceutical promotion expenditures in the United States." *PLoS Medicine*, 5(1): 2008.
154. White, Julie. "A National Public Drug Plan For All." Canadian Health Coalition. May 2016.
155. Chalkley, P. "Targeting accessible physicians." Canadian Pharmaceutical Marketing. April 2009.
156. Mintzes, B. et. al. "Pharmaceutical Sales Representatives and Patient Safety: A Comparative Prospective Study of Information Quality in Canada, France and the United States." *Journal of General Internal Medicine*, 28(10): October 2013.
157. Lexchin, Joel and Barbara Mintzes. "The pharmaceutical advertising code should be updated." Healthy Debate. 10 August 2016.
158. Gettings, Jenner et. al. "Differences in the Volume of Pharmaceutical Advertisements between Print General Medical Journals." *PLoS One*, 9(1): 8 January 2014.
159. Herder, Matthew and David Juurlink. "Let the Sun Shine on Doctors' Ties to Pharma." *Toronto Star*. 9 May 2016.
160. McLean, Jesse and David Bruser. "Drug Dinners for Physicians under New National Rules." *Toronto Star*. 14 March 2016.
161. Bruser, David, Jesse McLean, and Andrew Bailey. "Drug Companies Wine and Dine Family Physicians." *Toronto Star*. 16 February 2016.
162. Weeks, Carly. "Medical Association Takes Heat for Pfizer Funding." *The Globe and Mail*. 28 February 2011.
163. Blackwell, Tom. "Family-doctor College Releases Long-secret Report on Big-Pharma Funding, but Refuses to Cut off Money Flow." *National Post*. 4 January 2016.
164. Ibid.
165. Bowman, M.A. and D.L. Pearle. "Changes in drug prescribing patterns related to commercial company funding of continuing medical education." *Journal of Continuing Education in the Health Professions*, 8(1): January 1988.
166. Gagnon, Marc-André. "The Economic Case for Universal Pharmacare: Costs and Benefits of Publicly Funded Drug Coverage for all Canadians." Canadian Centre for Policy Alternatives. 13 September 2016.
167. Silversides, Ann. "Ontario's law curbing the cost of generic drugs spark changes." *Canadian Medical Association Journal*, 181 (3-4), 4 August 2009: E43-E45.
168. Beeby, Dean. "Revenue Canada Probe of Pharmacies Finds \$58M in Hidden Income." CBC. 7 July 2016.
169. Gagnon, Marc-André. "The Economic Case for Universal Pharmacare: Costs and Benefits of Publicly Funded Drug Coverage for all Canadians." Canadian Centre for Policy Alternatives. 13 September 2016.
170. Armstrong, David. "Secret trove reveals bold 'crusade' to make OxyContin a blockbuster." STAT News. 22 September 2016.
171. Ryan, H., L. Girion, and S. Glover. "More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew." *LA Times*. 10 July 2016.
172. Ryan, H., L. Girion, and S. Glover. "You Want A Description of Hell? Oxycontin 12-Hour Problem." *LA Times*. 5 May 2016.

173. Ryan, Harriet. "Purdue Pharma issues statement on OxyContin report; L.A. Times responds." *LA Times*. 6 May 2015.
174. Vowles, Kevin E., et. al. "Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis." *Journal of Pain*, (156)4: April 2015
175. Milne, V., J. Tepper, and M. Nolan. "5 ways the health system can curb the opioid epidemic." *Healthy Debate*. 22 September 2016.
176. Blackwell, Tom. "The Selling of OxyContin." *National Post*. 12 November 2011.
177. Milne, V., J. Tepper, and M. Nolan. "5 ways the health system can curb the opioid epidemic." *Healthy Debate*. 22 September 2016.
178. Meier, Barry. "In Guilty Plea, OxyContin Maker to Pay \$600 Million." *New York Times*. 10 May 2007.
179. Whyte, L., G. Mulvihill, and B. Wieder. "Politics of pain: Drugmakers fought state opioid limits amid crisis." *The Centre for Public Integrity*. 21 September 2016.
180. Milne, V., J. Tepper, and M. Nolan. "5 ways the health system can curb the opioid epidemic." *Healthy Debate*. 22 September 2016.
181. Persaud, Navindra. "Questionable content of an industry-supported medical school lecture series: a case study." *Journal of Medical Ethics*, 40:6, 2014.
182. Ibid.
183. "OxyContin Task Force: Final Report." Newfoundland and Labrador Government. 30 June 2004.
184. Lexchin, Joel and Jillian Clare Kohler. "The danger of imperfect regulation: OxyContin use in the United States and Canada." *International Journal of Risk & Safety in Medicine*, 23, 2011.
185. Piggott, Thomas and Jia Hu. "Opioid Epidemic Requires National Response." *Toronto Star*. 30 April 2016.
186. Bracken, Amber. "A Killer High: How Canada Got Addicted To fentanyl." *The Globe and Mail*. 8 April 2016.
187. Brosnahan, Maureen. "Opiate Overdose Deaths Rising across Canada." *CBC*. 18 June 2014.
188. "Party Drug 'Purple Drank' a Dangerous Mix, Police Say." *CBC*. 14 May 2016.
189. Bracken, Amber. "A Killer High: How Canada Got Addicted To fentanyl." *The Globe and Mail*. 8 April 2016.
190. Milne, V., J. Tepper, and M. Nolan. "5 ways the health system can curb the opioid epidemic." *Healthy Debate*. 22 September 2016.
191. Herder, Matthew and David Juurlink. "Let the Sun Shine on Doctors' Ties to Pharma." *Toronto Star*. 9 May 2016.
192. "About prescription drug abuse." Government of Canada. 14 April 2016.
193. Herder, Matthew. "It's Time to Think beyond National Pharmacare." *Toronto Star*. 8 February 2016.
194. Cosgrove, L., S. Vannoy, B. Mintzes, and A.F. Shaughnessy. "Under the Influence: The Interplay among Industry, Publishing, and Drug Regulation." *Accountability In Research*, 23(5): 2016.
195. Lexchin, Joel. "Economics and industry do not mean ethical conduct in clinical trials." *Journal of Pharmaceutical Policy and Practice*, 6(11): 2013.
196. Oved, Marcho Chown. "Canadian medical journals hijacked for junk science." *Toronto Star*. 29 September 2016.
197. Goldacre, B., H. Drysdale, A. Powell-Smith, et. al. "The COMPare Trials Project." www.COMPare-trials.org. 2016.
198. "Clinical Trials: For My next Trick..." *The Economist*. 26 March 2016.
199. Baker, Monya. "1,500 Scientists Lift the Lid on Reproducibility." *Nature*. 28 July 2016.
200. Shnier, A., J. Lexchin, M. Romero, and K. Brown. "Reporting of financial conflicts of interest in clinical practice guidelines: a case study analysis of guidelines from the Canadian Medical Association Infobase." *BMC Health Services Research*, 16(383): 15 August 2016.
201. Ioannidis, John P.A. "Evidence-based medicine has been hijacked: a report to David Sackett." *Journal of Clinical Epidemiology*, 73: 2016.
202. Rosenberg, Harriet and Adrienne Shnier. "The Conflict of Interest Movement in Medicine, Part 1." *Our Right to Know Network*. 9 May 2016.
203. Cosgrove, L., S. Vannoy, B. Mintzes, and A.F. Shaughnessy. "Under the Influence: The Interplay among Industry, Publishing, and Drug Regulation." *Accountability In Research*, 23(5): 2016.
204. Matheson, Alastair. "Ghostwriting: the importance of definition and its place in contemporary drug marketing." *BMJ*, 354:i4578: 2016.
205. Sismondo, Sergio and Mathieu Doucet. "Publication Ethics and the Ghost Management of Medical Publication." *Bioethics*, 24(6): 2010.
206. Ibid.
207. Ibid.
208. Briggs C.L. and D.C. Hallin. *Making Health Public: How News Coverage Is Remaking Media, Medicine, and Contemporary Life*. Routledge. 2016.
209. Briggs C.L. and D.C. Hallin. "The Neoliberal Subject and Its Contradictions in News Coverage of Health Issues." *Social Text*, 25(4): 2007.
210. Herder, Matthew. "It's Time to Think beyond National Pharmacare." *Toronto Star*. 8 February 2016.
211. Gagnon, Marc-André. "The Economic Case for Universal Pharmacare: Costs and Benefits of Publicly Funded Drug Coverage for all Canadians." *Canadian Centre for Policy Alternatives*. 13 September 2016.

212. Ibid.
213. "Canada's high drug prices under review." *Canadian Medical Association Journal*, 22 August, 2016.
214. "Annexe D: global overview of the pharmaceutical industry." Office of Fair Trading. 2007.
215. Herder, Matthew. "Pharma Financialized." *Impact Ethics*, 25 September 2015.
216. O'Leary, P. "Credible deterrence: FDA and the Park Doctrine in the 21st century." *Journal of Food and Drug Law*, 68(2): 2013.
217. "Fact sheet – Expand Medicare: Pharmacare." Canadian Union of Public Employees. 21 February 2013.
218. Kohler, J.C., K. Moscou, and J. Lexchin. "Drug Safety and Corporate Governance." *Global Health Governance*, 8(1), 2013.
219. Morgan S.G., M.A. Gagnon, B. Mintzes, and J. Lexchin. "A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy in Canada." *Healthcare Policy*, 12(1) May 2016.
220. Boozary, Andrew and Joel Lexchin. "Big Pharma's Relationship with Your Doctor Needs Some U.S.-style Sunshine." *The Globe and Mail*. 26 March 2014.
221. "Corruption in the Pharmaceutical Sector: Diagnosing the Challenges." Transparency International. June, 2016.
222. Fierlbeck, Katherine. "The blurred roles of our pharmaceutical regulators." *Policy Options*, 13 July 2016.
223. Health Canada. "Pharmaceutical submission and application review fees as of April 1, 2014." Government of Canada. 31 March 2016.
224. Health Canada. "Health Canada's proposal to parliament for user fees and service standards for human drugs and medical devices program." Government of Canada. 26 March 2010.
225. Lexchin, Joel. "Drug safety and health Canada." *The International Journal of Risk & Safety in Medicine*, 22(1): January 2010.
226. White, Julie. "A National Public Drug Plan For All." Canadian Health Coalition. May 2016.
227. Picard, André. "'New' Drugs Too Often Offer Little New." *The Globe and Mail*. 17 March 2009.
228. Lexchin, Joel. "Postmarket safety in Canada: are significant therapeutic advances and biologics less safe than other drugs? A cohort study." *BMJ*, 4:e004289: 2014.
229. "Increasing Drug Costs: Are we getting good value?" Therapeutics Initiative. 31 July 2006.
230. Lexchin, Joel. *Private Profits Versus Public Policy: The Pharmaceutical Industry and The Canadian State*. University of Toronto Press, 2016.
231. Auditor General of Canada. "2011 Fall Report. Chapter 4 – Regulating Pharmaceutical Drugs – Health Canada." Government of Canada. 22 November 2011.
232. Lexchin, Joel. "Health Canada's Use of its Priority Review Process for New Drugs: A Cohort Study." *BMJ*, e006816: 2015.
233. Lexchin, Joel. "New Drugs and Safety: What Happened to New Active Substances Approved in Canada between 1995 and 2010?" *Archives of Internal Medicine*, 172(21): 2012.
234. "Bill C-17: An Act to amend the Food and Drugs Act, Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)." Government of Canada. 6 November, 2014.
235. Herder, Matthew. "Reinstitutionalizing transparency at Health Canada." *Canadian Medical Association Journal*, 2015.
236. Bruser, D. and J. McLean. "Health Canada hands over documents but muzzles doctor." *Toronto Star*. 14 October 2015.
237. Graham, D.J. et. al. "Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal anti-inflammatory drugs: nested case-control study." *Lancet*, 365(9458): February 2005.
238. "Vioxx: lessons for Health Canada and the FDA." *Canadian Medical Association Journal*, 172(1): 4 January 2005.
239. Herder, Matthew. "It's Time For Big Pharma To Open Up About Drug Safety And Effectiveness." *The Huffington Post*. 17 February 2016.
240. Herder, M., T. Lemmens, J. Lexchin, L. Mintzes, and T. Jefferson. "Is pharmaceutical transparency in Canada all just talk?" *Policy Options*, 12 July 2016.
241. Herder, Matthew. "It's Time to Think beyond National Pharmacare." *Toronto Star*. 8 February 2016.
242. Morgan S.G., M.A. Gagnon, B. Mintzes, and J. Lexchin. "A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy in Canada." *Healthcare Policy*, 12(1) May 2016.
243. Schoen, Cathy and Robin Osborn. "The Commonwealth Fund 2012 International Health Policy Survey of Primary Care Physicians." Commonwealth Fund. November 2012.
244. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, J.R. Daw, and J. Lexchin. "Pharmacare 2020: The future of drug coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
245. Butler, M. and M. Barlow. "Foreword To The Third Edition." *Social Determinants of Health Canadian Perspectives*. Canadian Scholars Press, 2016
246. "Prescription Drug Access and Affordability an Issue for Nearly a Quarter of All Canadian Households." Angus Reid Institute. 15 July 2015.
247. "FCM and BC Chamber of Commerce endorse National Pharmacare program." Lobby Monitor. 10 June 2016.
248. Canadian Federation of Nurses Unions. "Summary of CFNU's Parliamentary Breakfast Filling the Prescription: The case for pharmacare now." 31 May 2016.

249. "Pharmacare in Canada." Aon Hewitt Inc. January 2016.
250. Canadian Union of Public Employees. "Submission to the House of Commons Standing Committee on Health Development of a National Pharmacare Program." September 2016.
251. Morgan, S.G., D. Martin, M.A. Gagnon, B. Mintzes, J.R. Daw, and J. Lexchin. "Pharmacare 2020: The future of drug coverage in Canada." Pharmaceutical Policy Research Collaboration. 15 July 2016.
252. Trudeau, Justin. "Minister of Health Mandate Letter." Government of Canada. November 2015.
253. "A New Plan for a Strong Middle Class." Liberal Party of Canada. 2015.
254. Morgan, S. and K. Booth. "Universal prescription drug coverage in Canada: Long-promised yet undelivered." *Healthcare Management Forum*, 1(8): October 2016.
255. "Policy Resolution E-09 Pharmacare." Liberal Party of Canada. May 2016.
256. Duggan, Kyle. "MPs Begin Study on Pharmacare, Warned of High Drug Costs." *iPolitics*. 13 April 2016.
257. "Pharmacare Vetoed As Costly." *Blacklocks Reporter*. 13 April 2016.
258. Morgan, S. and K. Booth. "Universal prescription drug coverage in Canada: Long-promised yet undelivered." *Healthcare Management Forum*, 1(8), October 2016.
259. Canadian Federation of Nurses Unions. "Summary of CFNU's Parliamentary Breakfast Filling the Prescription: The case for pharmacare now." 31 May 2016.
260. Silas, Linda. "Canada's Nurses Push for Bold Vision on Prescription Drugs." *National Newswatch*. 19 January 2016.



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