Rejoinder by the Canadian Health Coalition

to the testimony at the Standing Committee on Health of the Parliament of Canada (HESA) by

Innovative Medicines Canada and The Canadian Life and Health Insurance Association

Regarding the Development of a National Pharmacare Program

Canadian Health Coalition

By Keith R. Newman

March 15, 2017

Rejoinder to Innovative Medicines Canada

Mr. Monteith, Vice-President Innovation and Health Sustainability for Innovative Medicines Canada spoke on behalf of patent holding pharmaceutical drug companies. He appeared on June 6, 2016. The comments below are a response to his testimony in the areas relevant to the discussion of a National Public Drug Plan, that is the cost of pharmaceuticals, in particular relative to other countries, access to medicines, safety, and proper prescribing.

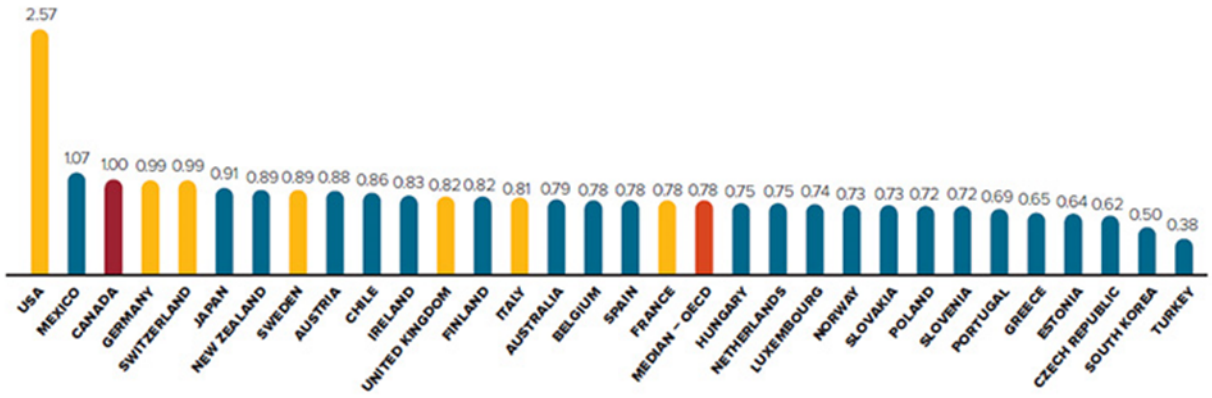
Canadian Prices Are Very High

Mr. Monteith asserted, citing the Patented Medicines Prices Review Board (PMPRB), that Canadian prices are lower than international prices by 13% (median price) or 31% (average price). However this is based on a very particular quote, comparing a small, very selective, group of countries.

Here is the general assessment of the PMPRB: "In 2015, Canadian prices were 28% higher that the median OECD price. Canada has some of the highest prices in the world. When independent data sources are used, all other countries in the PMPRB basket of comparators (with the exception of the US) have lower prices (on average) than Canada." [1]

Mr. Monteith also stated Canadian prices are third highest of eight comparator countries. This is misleading because our prices are third highest of 31 OECD countries as shown in the figure below.

Source: PMPRB Annual Report 2015, p. 30.



Furthermore we are going in the wrong direction.

[1] PMPRB Annual Report 2015, p.10.

Over the last 10 years, Canadian prices have gone up compared to the PMPRB seven comparator countries, except the United States. In 2005 prices were, on average, approximately equal to or below corresponding prices in all comparators other than Italy. By 2014, Canadian prices were decidedly above prices in the United Kingdom, France and Italy, and somewhat higher than prices in Sweden and Switzerland.[2]

Competitive products have caused prices to drop over 27 years

Mr Monteith asserts that "For 25 of 27 years under the PMPRB regulation, patented medicines' price increases were less than the consumer price index. What this means is that medicines have become more affordable over time relative to inflation".

While this statement is correct it simply reflects the mandate of the PMPRB to ensure that the price of patented pharmaceuticals increases at no more than the consumer price index (CPI). In fact the PMPRB believes prices should rise more slowly than the CPI:

> *Every country has an interest in ensuring that pharmaceutical prices are stable and predictable over time. In Canada, this is reflected in the Act and Guidelines to the extent that patented drug prices cannot increase by more than average inflation (as measured by CPI) in a given year. However, other countries, such as France, Sweden and Switzerland, take a more stringent approach in that pharmaceutical prices either cannot increase or must decrease at specified intervals. This makes sense given that, over time, both the marginal cost of producing a drug should be expected to decrease and price competition from subsequent drugs is felt in the market. Policies which normalize such expectations stand out as good examples of consumer protection.*[3]

Most New Drugs Are the Same as the Old

Mr. Monteith is critical of the time it takes for new medications to be included in the formularies of public plans and calls for earlier access to "innovative"

[2] PMPRB Annual Report 2015, p.29.
[3] PMPRB Guidelines Modernization: Discussion Paper, 2016; p.18

medicines. He implies that new "innovative" medicines are better than older ones and having access to them more quickly would mean better treatment sooner.

Unfortunately new is not usually better than old as the vast majority of new medicines are about the same as the old ones. Of 336 new active substances that Health Canada approved between January 1, 1997 and March 31, 2012 **only 9.2 per cent were significant therapeutic advances**.[4]

In addition, a recent US study found that new cancer drugs provide very little or no improvement over older drugs.

> *Overall cancer survival has barely changed over the past decade. The 72 cancer therapies approved from 2002 to 2014 gave patients only 2.1 more months of life than older drugs…*
>
> *And those are the successes.*
>
> *Two-thirds of cancer drugs approved in the past two years have no evidence showing that they extend survival at all, Prasad (*Dr. Vinay Prasad, assistant professor of medicine at the Oregon Health and Sciences University) *said….*
>
> *"We are very concerned about the push to get more drugs approved, instead of effective drugs approved," said Fran Visco, president of the National Breast Cancer Coalition, who said the last game-changing breast cancer drug, Herceptin, was approved nearly 20 years ago.*[5]

Given the lack of significant therapeutic improvement shown by 90% of new drugs the responsible course of action for public drug plans is to take the time to evaluate the effectiveness and cost of new drugs compared to older treatments before adding them to their formularies.

Below is Mr. Monteith's testimony before the Committee regarding the time it takes for new drugs to be added to public formularies:

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[4] Joel Lexchin, Postmarket safety in Canada: are significant therapeutic advances and biologics less safe than other drugs? A cohort study, BMJ Open. 2014; 4(2): e004289; http://pubmedcentralcanada.ca/pmcc/articles/PMC3931983/ Website accessed March 11, 2017

[5] Liz Szabo, Amid flurry of new cancer drugs, how many offer real benefits?, Kaiser Health News, February 9, 2017; http://edition.cnn.com/2017/02/09/health/hope-vs-hype-cancer-drugs-partner/index.html

The Broken Promise of Research and Development

When the pharmaceutical drug industry was allowed to expand monopoly pricing for patented drugs in 1986, it promised the Canadian government it would spend more on research and development (R&D). The industry has broken that promise. Research and development in Canada has fallen to historically low levels as shown by the PMPRB yet we currently pay $3.6 billion more annually for patented medicines than if we had paid average OECD prices. In effect the industry receives an annual subsidy of at least $3.6 billion for no reason.[6]

But Mr. Monteith believes we should still pay high prices because developing new drugs, in other countries, is costly. An alternative view would be that Canada should be paid compensation for decades of overly high prices justified by the false promise of investment in research and development.

What is the Cost of R&D?

According to Mr. Monteith the cost of research to bring a new drug to market is $2.6 billion US:

"Today, Tufts University in Massachusetts, which generally maintains the biggest database on the cost of R and D for pharmaceuticals, estimates that the average drug coming to market—this is worldwide cost, mind you—cost about $2.6 billion U.S. The vast majority of that is in clinical trials, because of the costs and sophistication of those trials. As we get more targeted in our populations, we have to do a lot more sophisticated trials to show the evidence that they work".

But if you believe the figure of $2.6 billion "you probably also believe the earth is flat" according to Médecins sans frontiers (MSF). MSF also notes that "the cost of developing products is variable, but experience shows that new drugs can be developed for as little as $50 million, or up to $186 million if you take failure into account, which the pharmaceutical industry certainly does".[7]

[6] PMPRB Guidelines Modernization: Discussion Paper, 2016; p.17

[7] Médecins sans frontières, R&D cost estimates - MSF response to Tufts CSDD study on cost to develop a new drug, 18 November, 2014; at https://www.msfaccess.org/content/rd-cost-estimates-msf-response-tufts-csdd-study-cost-develop-new-drug

The study quoted by Mr. Monteith is not credible. It was produced by a centre that receives much of its funding from the pharmaceutical drug industry. It considered only a small number of the most costly research projects and used secret data. As well, it added to the research costs the profits the industry could have made had it successfully speculated in financial assets instead of conducting drug research ($1.2 billon of the $2.6 billion). This is very misleading. It is not an out-of-pocket expense and is not what a layperson normally thinks of as a cost. It is the returns that might be expected, but that investors went without, while a drug was in development. While it's possible that a drug company might have been able to make more money by investing in other areas, if it doesn't invest in research and development, it won't be a drug company anymore.[8]

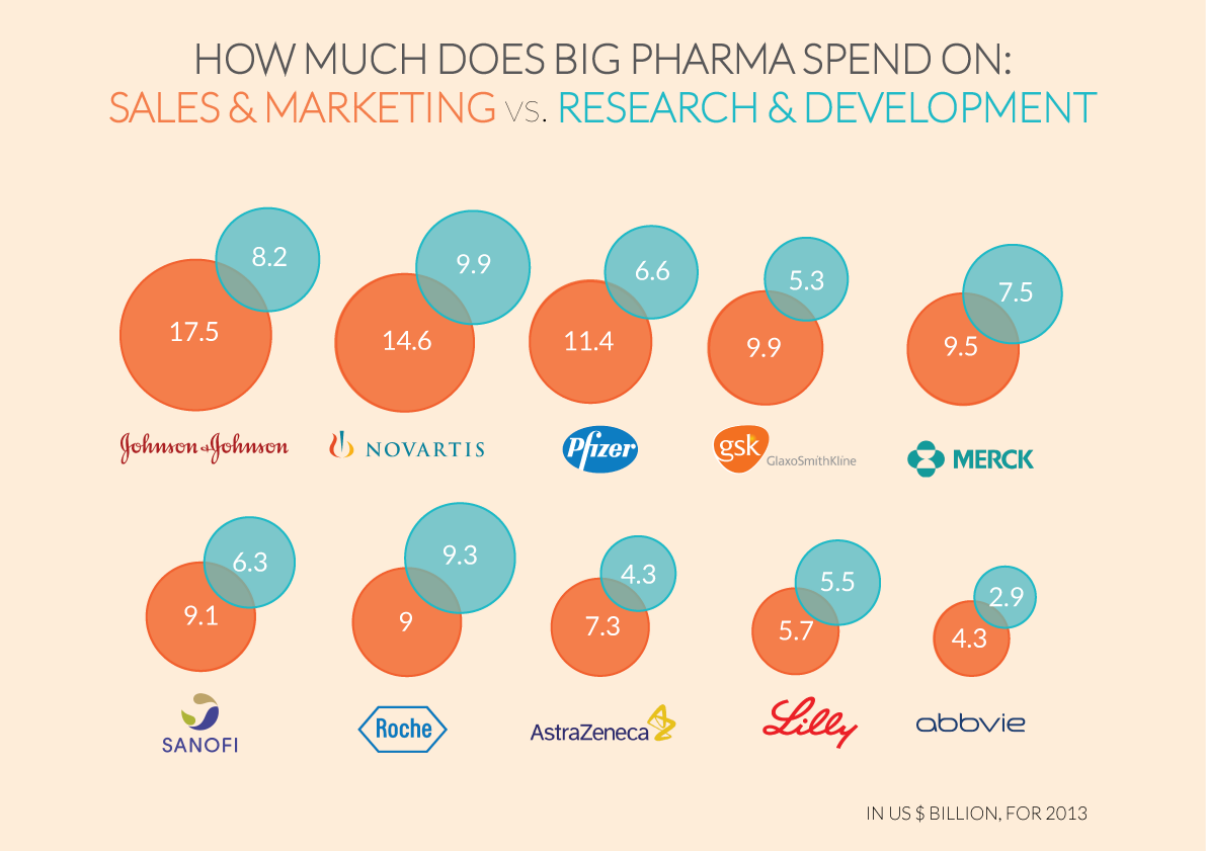
Drug Companies Spend More on Marketing than R&D

While Mr. Monteith implies the drug industry is primarily concerned with innovative research the reality is different. Nine of ten major drug companies spend more on marketing than research, as illustrated in the chart below.

The focus on marketing in fact discourages real innovation but does produce large profits. The industry conducts thousands of trials of existing drugs to expand the market into new indications rather than develop innovative new chemicals. The strategy works because marketing departments and large networks of sponsored clinical leaders succeed in persuading doctors to prescribe the new products.[9]

[8] Aaron E. Carroll, $2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions, New York times, November 18, 2014; https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html;

[9] Donald W Light et al., Pharmaceutical research and development: what do we get for all that money? BMJ 2012;344:e4348 doi: 10.1136/bmj.e4348, p.2; http://www.pharmamyths.net/files/BMJ-Innova_ARTICLE_8-11-12.pdf)



Source: Chart by León Markovitz at Dadaviz with data from the BBC.
http://www.vox.com/2015/2/11/8018691/big-pharma-research-advertising
The top circles represent research and development spending. The bottom circles represent sales and marketing spending.

Unlawful Promotion of Drugs: Billions in Criminal Fines and Settlements

The overriding focus by the industry on marketing has led it to unlawfully promote drugs and violate other criminal and civil statutes in the United States. From 2006 to 2015 the industry was required to pay $30 billion in settlements and criminal fines for the hundreds of violations it committed in that country.[10] In a high profile example, Merck aggressively marketed the painkiller Vioxx[11] despite some early evidence it might increase heart attacks. A scientist with the US Food and Drug Administration estimated that "88,000 to 140,000 excess cases of

[10]Paul Feldman,Drug Companies Pay Up in Illegal Marketing Cases, But Are Penalties Enough?, Business Ethics, May 5, 2016; http://business-ethics.com/2016/05/05/1606-drug-companies-pony-up-in-illegal-marketing-cases-but-critics-wonder-if-penalties-are-enough-see-more-at-http/
[11]Barry Meier and Stephanie Saul, Marketing of Vioxx: How Merck Played Game of Catch-Up, New York Times, Feb. 11, 2005; http://www.nytimes.com/2005/02/11/business/marketing-of-vioxx-how-merck-played-game-of-catchup.html?_r=0

serious coronary heart disease probably occurred in the US over the market life of rofecoxib,…"[12] If US figures are extrapolated to Canada Vioxx could have been associated with as many as 4,000 to 7,000 deaths here.[13]

Vioxx was sold from 1999 until the company withdrew it in 2004. Canadian victims finally received settlement for damages in 2016.[14]

Why new drugs are usually no more effective than old ones

Our current patent system for drugs is archaic and stifles innovation. The incentives it provides are misguided:

-drug companies have a strong incentive to copy existing drugs in order to capture a share of the profits made by a competitor rather than developing new innovative drugs.

-monopoly patents slow the research process by encouraging secrecy, yet research advances most quickly when it is open.

-research is directed toward finding a patentable product. If evidence suggests that a condition can be most effectively treated through diet, exercise, environmental factors, or even old off-patent drugs, a pharmaceutical manufacturer has no incentive to pursue this research.[15]

We Need a New System for Real Innovation

An expanded system of publicly financed, open medical research would lead to the development of a greater number of effective new drugs. This is not the place to discuss such a project but suffice it to say that the current system is a failure and alternatives do exist. The Canadian Health Coalition encourages the Standing Committee on Health to investigate alternative systems for truly innovative drug research in its future work.

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[12] Shaoni Bhattacharya, Up to 140,000 heart attacks linked to Vioxx,New scientist, January 25, 2005; https://www.newscientist.com/article/dn6918-up-to-140000-heart-attacks-linked-to-vioxx/

[13] Vioxx took deadly toll: study, Globe and Mail, Jan. 25, 2005; accessed March 11, 2017; http://www.theglobeandmail.com/life/vioxx-took-deadly-toll-study/article1113848/

[14] Mishkin Law Personal Injury Lawyers, Vioxx class action settlement now paid, October 1, 2016; at http://adrworks.com/vioxx/vioxx-class-action-settlement-now-paid/

[15] Dean Baker, "Drugs are Cheap: Why Do We Let Governments Make Them Expensive? ", February 13, 2017; http://cepr.net/publications/briefings/testimony/drugs-are-cheap-why-do-we-let-governments-make-them-expensive

Rejoinder to the Canadian Life and Health Insurance Association

Mr. Frank Swedlove, President and Chief Executive Officer, Canadian Life and Health Insurance Association and Mr. Stephen Frank, Vice-President, Policy Development and Health for the Canadian Life and Health Insurance Association Canada spoke for the insurance industry. They appeared on May 9, 2016.

The High Cost of Private Insurance

Mr. Frank was asked to respond to the 2014 study published in the Canadian Medical Association Journal by Michael Law et al. regarding the administrative costs of private group insurance plans. The researchers calculated the cost of plans which include an insurance component, meaning that if an employee develops an illness requiring costly drug treatment the high cost is covered by insurance rather than by a drastic increase in the plan premiums. The study estimated the medical loss ratio for this insurance at 74%, meaning that for every dollar paid to the insurance company only 74 cents is returned in health benefits.[16]

In his testimony Mr. Frank indicated this was an overestimate since the figures used included other insurance benefits. Law et al. did note in their article that full information was not publicly available and a completely accurate calculation was not possible. As an aside we note this observation illustrates a serious problem with private insurance plans, namely their lack of transparency. With respect to the insurance industry medical loss ratio Mr. Frank himself estimates the ratio to have been 82% in 2012, meaning for each dollar paid to the insurance company only 82 cents was returned in benefits.[17] The 18% not spent on benefits consisted of the amount spent on administration, the amount kept as profit and other nonmedical spending.

This is much higher than the administration costs reported by the Quebec public drug plan where fully 98.4% of the funds collected were returned in benefits in the 2015-2016 fiscal year. With the administration costs of the Quebec public

[16] Original article by Law et al.: The increasing inefficiency of private health insurance in Canada, *CMAJ September 2, 2014 vol. 186 no. 12; http://www.cmaj.ca/content/186/12/E470.long*

[17] Stephen Frank, Correcting the Record, *CMAJ July 8, 2014 vol. 186 no. 10* doi: 10.1503/cmaj.114-0053; http://www.cmaj.ca/content/186/10/779.1

plan at 1.6%[18], a comparison of the two shows that the administration costs of private plans are 11 times greater than those of the Quebec public plan (1.6% versus 18%).

Access to New Drugs

In his testimony Mr. Swedlove stated that "… private insurers generally provide Canadians with access to far more drugs than public plans, and we allow access to new drugs much more quickly than public plans". He presented this as a plus for Canadians with private insurance coverage.

Yet we know most new drugs are no better than the old so greater access to new drugs is not an advantage per se.[19]

Best practice would be to compare the new drugs as they come out with the old and cover the few that are significantly better as well as those that are no better but are more cost effective.

The insurance industry does not do this. Policies often cover all approved drugs regardless of their benefits. The result is coverage of new and expensive drugs that provide no benefit over existing less costly therapies. This is one reason private insurance coverage leads to $5 billion of wasted spending on pharmaceuticals every year (see below).

Private Insurance Wastes $5 Billion Yearly

> *Although many Canadians have private drug coverage, the insurance companies offering those plans lack the financial incentives, negotiating capacity, and clinical authority necessary to effectively control prices and manage the allocation of expenditures across competing demands for healthcare…*
>
> *These characteristics of private drug insurance (in the context of Canada's public healthcare system) result in extraordinary waste: private sector analysts estimate approximately $5 billion per year spent by employers on*

[18] $58.5million on a total budget of $3,544.5 million for the 2015-2016 fiscal year; http://www.ramq.gouv.qc.ca/SiteCollectionDocuments/citoyens/fr/rapports/rappann1516.pdf; pp.55-6

[19] See the paragraph above entitled " Most New Drugs Are the Same as the Old" in the rejoinder to Mr. Monteith.

drug benefits is wasted because private drug plans are not well-positioned to manage drug prices, cost-effectiveness, or the prescribing and dispensing decisions of Canadian health professionals [20]

Private Insurance is Unnecessary and Undermines Public Plans

Insurance companies play no role in the public's access to doctors and hospitals under currently existing medicare. For drugs, insurance company middle-men are also unnecessary.

Indeed, while private insurers provide no benefit over a public plan they do give rise to serious problems:

-very high administration costs;

-waste of $5 billion yearly by reimbursing medicines that are more expensive without additional therapeutic value, or because they pay unnecessary dispensing fees.

-undermining of public plans by "skimming", that is they cover the less costly "good risks" (richer, healthier, younger), and leave the more costly "bad risks" (unable to work, low-income, seniors) to public plans.[21]

[20] Steve Morgan et al., *A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy* in CanadaHealthcare Policy, 12(1) May 2016: 18-36.doi:10.12927/hcpol.2016.24637.; http://www.longwoods.com/content/24637

[21] Marc-André Gagnon, A Roadmap to a Rational Pharmacare Policy in Canada, p.27, The Canadian Federation of Nurses Unions, 2014; available at https://nursesunions.ca/sites/default/files/pharmacare_report.pdf