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BRIEF TO THE HOUSE OF COMMONS STANDING COMMITTEE ON HEALTH REGARDING THE PATENTED MEDICINE PRICES REVIEW BOARD GUIDELINES

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Thank you for the opportunity to appear before the House of Commons Standing Committee on Health to present my views about the Patented Medicine Prices Review Board guidelines.

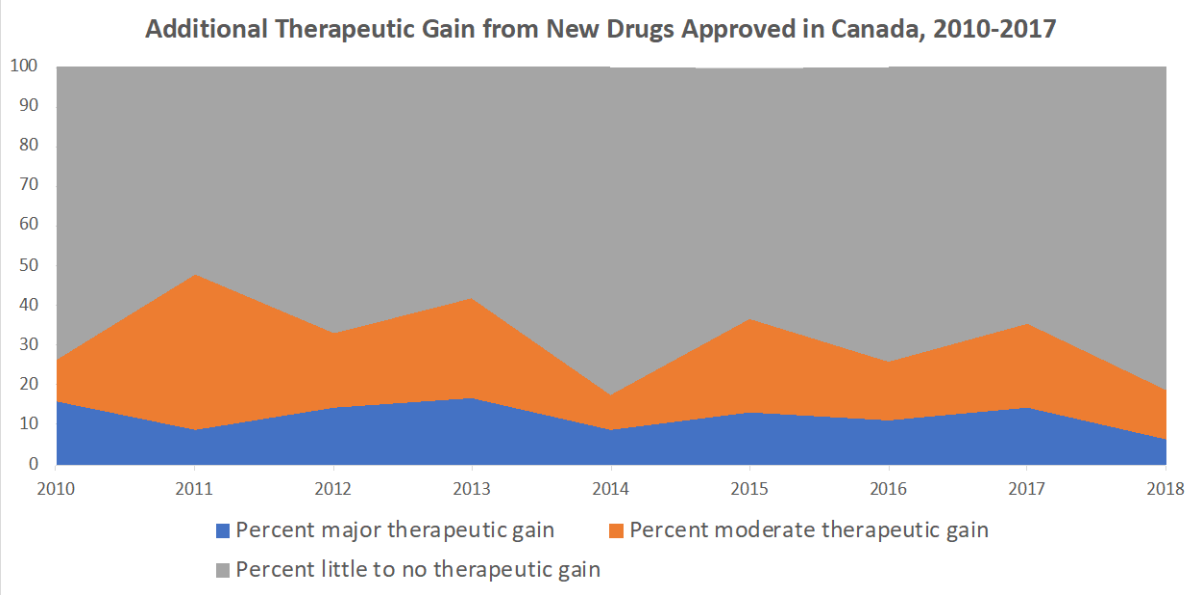
My name is Joel Lexchin and I have worked as an emergency physician at the University Health Network since 1988. In addition, I taught health policy at York University from 2001-2016 and I have been researching and writing about pharmaceutical policy for 40 years. I have written 4 books and authored or co-authored over 220 peer-reviewed journal articles on various aspects of pharmaceutical policy.

Introduction

This brief will focus on the issue of whether or not the changes to guidelines of the Patented Medicine Prices Review Board will affect the ability of Canadian patients to receive medicines at an affordable price that will improve the quality of their lives and/or help them live longer.

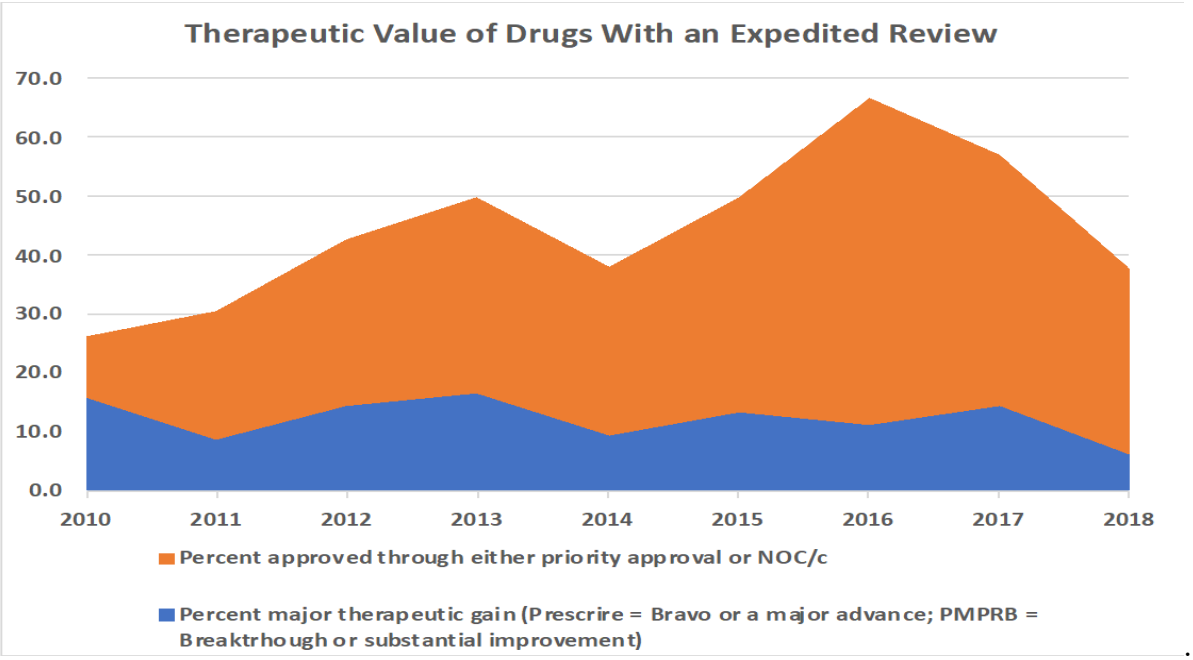
1. Therapeutic Value of New Drugs

To begin with, it is necessary to realize that most of the new drugs (new chemical entities – products never marketed before in Canada in any form) are not significant therapeutic advances over already existing medicines. Only about 10% of the new drugs that are marketed in any given year are significant therapeutic advances. Figure 1 below summarizes the percent of drugs with a significant therapeutic gain over the time period 2010 to 2018.



The therapeutic ratings in this figure are based on evaluations by the Human Drug Advisory Panel of the PMPRB and the independent French drug bulletin *La revue Prescrire*.

What's true for drugs in general is also true for drugs that Health Canada expedites through the regulatory review pathway by either speeding up the review (Priority Review) or by approving the drug based on incomplete evidence (Notice of Compliance with conditions). In both cases Health Canada believes that these products have the potential to help treat illnesses where currently there is no treatment or where the available products are not optimally effective and/or safe. Figure 2 below shows that although up to almost 70% of drugs can receive an expedited review in any given year, only about 10% of those drugs are significant therapeutic advances.



Finally, there are drugs that are termed "first in class", i.e., there are no other products that are similar to them. Even in this case only 1 in 6 are significant therapeutic advances.

Conclusion: An objective analysis of the therapeutic value of new drugs is that only a small minority offer significant new benefits to Canadian patients.

2. Availability of Drugs for Orphan Diseases

The argument is being advanced that companies will not introduce drugs for orphan diseases if the guidelines, as written, come into force. The claim is that the guidelines will lower prices to such a degree that it will no longer be profitable for companies to introduce these products.

Thirty years ago, the idea that drugs for orphan diseases were not profitable may have had some merit but this is no longer the case. In fact, as the table below shows drugs that have an orphan designation for some or all indications (i.e., those identified by an *) are some of the most profitable drugs in the world.

Table 1: Top 10 pharmaceutical medications forecast as worldwide sellers in 2015, listed in order of the top projected 2015 sales

Brand name	Company	Therapeutic area	Worldwide sales 2015 ($US billions)
Sovaldi + Harvoni	Gilead	Hepatitis C	15.3
Humira*	AbbVie	Immunosuppressant	14.1
Lantus	Sanofi	Diabetes	8.0
Rituxan*	Roche	Cancer	7.6
Avastin*	Roche	Cancer	7.2
Herceptin	Roche	Cancer	6.6
Seretide/Advair	GlaxoSmithKline	Asthma	6.3
Remicade*	Johnson & Johnson	Immunosuppressant	6.0
Revlimid*	Celgene	Cancer	5.7
Crestor*	AstraZeneca	Homozygous familial hypercholesterolemia	5.2

(Source: Daniel et al. The orphan drug act: restoring the mission to rare diseases. American Journal of Clinical Oncology 2016; 39:210-213.)

What about the introduction of drugs for orphan diseases in Canada? One way of examining this question is by comparing Canada to other similar countries that have lower prices. According to the 2018 annual report from the PMPRB, drug prices in Australia are on average 25% lower than those in Canada. Are there fewer drugs for orphan diseases being introduced in Australia compared to Canada because of the lower prices? This question has been investigated (i.e., Lexchin et al. Does an orphan drug policy make a difference in access? A comparison of Canada and Australia. International Journal of Health Services 2019;50:166-172). From the start of 2008 to the end of 2017, the US Food and Drug Administration approved 119 drugs for orphan diseases. Out of that total, Health Canada and the Australian Therapeutic Goods Administration both approved 71 of these drugs; Health Canada approved an additional 11 that were not approved in Australia and the TGA approved an additional 4 that were not approved in Canada. Overall there was no statistical difference in the number of drugs approved in the two countries.

Some groups and individuals have focused on one particular drug, Trikafta, a breakthrough drug for the treatment of cystic fibrosis. The company making the drug did not allegedly submit it for approval to Health Canada because it felt that it would not get the price that it wanted. In the US, Vertex is charging $311,000 per year ($411,000 Canadian). However, the independent Institute for Clinical and Economic Review, which assesses value for money, estimates that based on the amount of improvement in overall health patients receive from Trikafta, the highest price should be between $67,900 and $85,500 per year, i.e., the price should be discounted by 73% to 78%. Vertex cut a deal with the United Kingdom's National Health Service to market Trikafta at a lower (but undisclosed) price and did the same thing in Switzerland for two of its other cystic fibrosis drugs. The ability of other countries to get reduced prices shows that companies will still introduce drugs even at lower prices.

Conclusion: There is no reason to believe that lower Canadian prices will mean that drugs for orphan diseases will not be introduced in Canada.

3. Companies Will Delay the Launch of New Drugs

There have been a variety of claims that companies will delay the launch of new drugs onto the Canadian market or not launch them at all because of reduced prices. Typical of these claims is the one from Life Sciences Ontario (LSO) in a webinar on June 22, 2020. One of the slides presented by LSO said that "Early evidence points to a significant change in 2019 with a major drop in new launches, directly opposite of global trends."

The PMPRB announced its intention to revise its regulations in 2016 and it might be expected that companies would have already either decreased or delayed launches but the evidence to date shows that this has not happened as the table below shows.

Percent of drugs approved and launched 2014-2019 and median time to launch

Year	Approvals	Launches (%)	Median time to launch in days (IQR)
2014	26	25 (78%)	47 (15, 290)
2015	37*	34 (92%)	68 (32, 159)
2016	36	31 (86%)	54 (22, 172)
2017	36	32 (89%)	62 (29, 112)
2018	39	35 (90%)	62 (36, 134)
2019	36	26 (72%)	58 (40, 163)

*Marketing approval cancelled before 2 drugs launched

While the percent of drugs approved in 2019 that have been launched is below the figure for the previous 4 years it is in line with the figure for 2014, before the PMPRB announcement. Moreover, to date there has not been any change in the median time between approval and launch.

Conclusion: To date, the claim that companies will either not launch new drugs onto the Canadian market or will delay their launch has not been proven.

4. Patient Groups

Patient groups have been set up in Canada to represent patients at multiple levels in the healthcare system and more widely. Typically, they are concerned with people suffering from a single condition, but they may also represent people with multiple related conditions, e.g., various forms of arthritis. They may lobby for Health Canada to approve new drugs and for particular products to be provided for their members. They also speak for patients with healthcare professionals and healthcare institutions such as hospitals and finally they are often the voice of patients in the media.

Since the Canadian federal government rolled back funding of patient groups in the mid 1990s, some patient groups have had to seek new sources of revenue and many of them receive money from pharmaceutical companies. Some industry-sponsored patient groups have lobbied against the introduction of the new PMPRB guidelines. The question is whether the conflicts-of-interest that patient groups have because of their funding influences their viewpoints about whether or not medications should be publicly funded.

The question about the views of patient groups has been analyzed by looking at the submissions that these groups make to the Common Drug Review (CDR) and the panCanadian Oncology Drug Review (pCODR) (Lexchin. Association between commercial funding of Canadian patient groups and their views about funding of medicines: an observational study. PLoS One 2019;14:e0212399). Up until mid-2018, 93 patient groups made a total of 372 submissions to the CDR and/or pCODR. Groups declared a total of 1896 conflicts with drug companies in 324 submissions. In 90% of submissions the patient groups supported public funding of the medication in question.

pCODR did not recommend public funding in 19 of its decisions and in 17 of those 19 (89.4%), patient groups disagreed with the decision. In 51 cases where pCODR recommended public funding there were only 3 times when patient groups disagreed with that decision, usually because pCODR recommended funding with conditions and the patient groups found the conditions too restrictive.

Conclusion: In evaluating the testimony from patient groups that receive funding from pharmaceutical companies, the House of Commons Standing Committee on Health should consider their conflicts-of-interest.

FINAL CONCLUSION

I strongly support the introduction of the new PMPRB guidelines as one step in making prescription medications more affordable for Canadians.