PMPRB Consultation, December 20, 2023
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Key Points

- Excessive drug prices distort the allocation of public resources, putting fair and sustainable health care systems at risk.
- Public and private sector actors have different societal roles that can be in conflict. Structural factors at the PMPRB consultations, and now within the PMPRB board, favour the private sector.
  Patient advocacy groups with funding from the pharmaceutical industry have intervened to challenge the PMPRB's initiatives to control drug prices, repeating industry claims that patients will suffer if prices are controlled, when the evidence does not support these claims. To ensure the PMPRB's work is based on evidence, the agency must be free to challenge dubious claims, whether made by the industry, patient advocates, and other intervenors.
  The PMPRB needs to reinforce and act on its mission, which is to effectively cap Canada's excessive drug prices.

Background

This submission incorporates and expands on material from my roundtable presentation on December 5.[1] I receive no funding from the pharmaceutical industry and none of the projects I work on are industry funded.

My interest in drug policy began with my first cancer diagnoses 35 years ago. Professionally, I have worked as a journalist, an academic, and a cancer patient advocate. My current work combines all these roles. As a patient advocate in the 1990s, I argued that patients should have a voice at public policy tables. For two decades I have studied and written extensively about partnerships between patient advocacy groups and pharmaceutical companies, and the policy implications of these alliances. This interest informs my engagement with the PMPRB and drug pricing.[2]

Six years ago, I joined with a group of colleagues from across the country to form *Independent Voices for Safe and Effective Drugs* (IVSED). We became regular intervenors[3] supporting the PMPRB regulations and the proposed guidelines because we were dismayed at the lack of public sector intervenors arguing that Canada's high drug prices must be reined in. Our drug prices have long been the 3rd highest in the world; I understand we're now in second place.

Unfairly priced drugs prices are obviously a problem to the people who need effective medications and can't afford them. But beyond those affected directly, all Canadians have a vested interest in a publicly funded healthcare system that is fair

and sustainable. Excessive drug prices distort the allocation of public resources throughout the health care system.

"Stakeholders," Partnerships, and the PMPRB consultations

My comments are primarily addressed to Theme 6 of the scoping paper, the PMPRB's engagement with "stakeholders who are not rightsholders." I find the term and concept of public intervenors as "stakeholders" both misleading and a source of problems in the PMPRB's efforts to engage with the broader public. I would urge everyone at the PMPRB to read a short article called "Banishing Stakeholders," by Joshua Sharfstein.[4] Dr. Sharfstein is a former senior administrator at the U.S. FDA. He writes that, in health policy, a catch-all phrase like "stakeholder" obscures the uneven landscape by putting lobbyists and representatives from industries with a financial interest in health policies on the same footing as those advocating for the public interest. His critique recognizes that the public and private interest in health represent two different value systems that are sometimes in conflict. Advocates for the private interest also have vastly more resources than most advocates for the public interest. As participants in the turbulent process about the PMPRB Guidelines over the past years, my colleagues and I, who participated as unfunded volunteers, felt this false equivalence keenly.

Dr. Sharfstein describes the rise of a "stakeholder management" industry that counsels health policy makers in how to "make stakeholders happy." But the purpose of good health policy is not to please stakeholders, but to "advance the health of the public at reasonable cost."

Lawyer/ethicist Jonathan Marks, takes up this misalignment in his book *The Perils of Partnership.*[5] Governments, including ours, have blurred the boundaries of public and private interests, with a policy culture that encourages partnerships between private corporations and the agencies tasked with regulating them.

Marks argues that these partnerships inevitably weaken public health policy, because the core responsibility of government health agencies is to *actively guard the public health*. To do this, public health agencies may have to engage in struggle and even direct conflict with private companies – whose core responsibility is to sell their product and make profits for shareholders. Engaging in conflict with the private sector is not about demonizing industry. It simply recognizes that both parties have responsibilities that are fundamentally at odds; the private sector has enormous resources and deploys well-honed profit-seeking strategies.

The partnership culture that Marks warns of is alive and thriving in Canada's health system. I was dismayed at the appointment of individuals from the private sector to the two top positions on the PMPRB board. Echoing Jonathan Marks: this is not to discredit PMPRB chair Thomas Digby, or vice-chair Anie Perrault. But I don't to see how the PMPRB can engage in the struggle necessary to bring down

Canada's drug prices when this means confronting colleagues in the pharmaceutical and biotech sectors.

Research on Patient Advocacy Groups and Pharma Partnerships

Patient advocacy groups (PAGs) are also part of the partnership culture. Partnerships between patient groups and pharma companies are central to my research and advocacy. Scholarly and journalistic accounts of these partnerships are now extensive, and the findings are consistent – and concerning. PAGs have become a powerful force in shaping drug policies throughout the high-income world[6]; most now accept funds from pharma companies,[7] some have staff and board members who worked or currently work for pharma companies,[8] transparency about the relationships is inadequate.[9]

The position that industry-funded groups take on drug pricing generally reflects a belief that drugs should be subject to the free market, while the groups that do not accept funds from the industry see drugs as a public good: prices must be controlled to protect health systems and to ensure all patients that need them have access to beneficial drugs. Groups funded by the industry intervene regularly in drug policy arenas to support the industry's free market goals, including the right to charge what the market will bear for pharmaceuticals.

Industry-funded patient advocates give two reasons for opposing policies that could curtail drug profits:

a) that drug companies need large profits to provide innovative new therapies; and
~~b)~~ that government price negotiations will cause companies to delay launching their drugs in that country, or even to refuse to market their drugs in that jurisdiction.

As American physician and ethicist Carl Elliott points out, when patient advocates speak about the high cost of research and development, and delays in new drug approvals, they are simply repeating " pharmaceutical industry talking points that date back to the 1970s."[10]

In the U.S., the industry's most lucrative market, patient advocate David Mitchell last year called out the industry's use of these tired arguments to oppose government attempts to control American drug prices through the Inflation Reduction Act. Mitchell, who has multiple myeloma, founded Patients for Affordable Drugs Now, a group that does not accept funds from pharmaceutical companies. In an August 2022 letter to Congress, he responded to the claims of PhRMA, the U.S. pharmaceutical industry's lobby arm, that price regulation would cripple innovative research on cancer drugs and cause companies to stop marketing new drugs in the U.S. Mitchell pointed out that, of the 356 new drugs the FDA approved from 2010 to 2019, all 356 were based in part on research paid for by

taxpayers. And he called it "silly" to suggest drug companies would not stop marketing drugs in the largest market in the world with the highest prices in the world.[11]

In Canada, the play of free market versus public interest ideology was plain in the patient advocacy of two Canadian advocacy groups regarding the drug Procysbi, used to treat the rare condition cystinosis. The company Horizon priced Procysbi, with the active ingredient cysteamine, at over $300,000 for the Canadian market of approximately 100 patients. Horizon's decision to market Procysbi in Canada blocked the availability of Cystagon, an almost identical drug that had been available for $10,000 per patient per year through the federal Special Access Program. Erin Little, whose daughter was being treated with Cystagon, and who founded the group Liv-A -Little Foundation with her husband Chad, protested the price of Procysbi, despite the Ontario government agreeing to cover the cost, saying, "We must have higher expectations for pharmaceutical companies than price gouging patients and, more importantly, taxpayer dollars." By contrast, Durhane Wong-Rieger, the CEO of the Canadian Organization for Rare Disorders (CORD) said she did not think patient advocates have a responsibility to publicly pressure drug companies to lower their prices. Liv-a-Little Foundation is independent of the pharmaceutical industry while the Canadian Organization for Rare Disorders (CORD) receives funding from more than two dozen pharmaceutical companies, including Horizon.[12] In September 2022, the PMPRB ruled that Procysbi's price is excessive. Horizon was directed to reduce the price of Procysbi and to pay over $22 million to the Receiver General of Canada.[13]

Patient advocacy groups sometimes support price controls on pharmaceutical drugs, but rarely unless they are independent of the industry. These groups are the minority, they have limited resources, and their voices are easily dominated by those of industry-funded groups. The result is a dominant narrative that claims lower prices will harm patients, despite weak or absent evidence.

What do Canadian PAGs think of drug Prices in Canada?

Based on the extensive literature on patient advocacy groups, I wasn't surprised to see the extent to which patient advocates opposed and even attacked the PMPRB.[14] Yet I'm concerned: a less engaged observer might well conclude that patient advocates in Canada don't think our high drug prices are a problem.

But does their public advocacy reflect their actual views? Last May, an organization called Patient View, based in the UK, released its most recent report on what PAGs in Canada think of the pharmaceutical industry. Patient View conducts annual surveys of patient groups around the world, asking what they think about pharmaceutical companies. Last year they surveyed 122 patient groups in Canada, 93% of whom worked with pharma companies. Participants – who

could respond anonymously -- rated pharma companies on 14 scales, including whether the companies had "Fair Pricing Policies." Of the 14 activities rated, 'fair pricing policies' ranked dead last. Only 20% of the 122 groups said pharma's pricing policies were "good or excellent."[15]

How good or bad the pharma industry was at carrying out specific activities, Canada, 2022
% of respondent Canadian patient groups stating "Excellent" or "Good"

Figures just for 2022	
Products that benefit patients	68
Ensuring patient safety	65
Patient-group relations	60
Innovation	59
Integrity	51
Information	51
Patient centricity	49
Services 'beyond the pill'	44
Transparency: funding	39
Access to medicines	37
Transparency: pricing	35
Engaging patients in R&D	31
Transparency: clinical data	22
Fair pricing policies	20

Patient View's press release discussed the recent events at the PMPRB. It said high prices and access to medicines were the "predominant worries" for Canadian patient groups. A national respiratory-conditions patient groups is quoted as saying, "Stop fighting the PMPRB changes, and focus on bringing actual innovation to the table." Curiously, these concerns aren't reflected in the industry-funded patient advocacy group submissions to the PMPRB, or in media comments by leaders of patient groups.

Trikafta, Patient Advocacy in Canada, and Canadian Drug Spending

The most dramatic example of patient advocate opposition to the PMPRB concerned the drug Trikafta, for cystic fibrosis, a new entry to the Canadian market in 2021 and a prime example of a drug that merited public discussion of price. Trikafta is highly effective; however, Vertex, the company marketing the drug, garnered international headlines for pricing the drug at over U.S.$300,000/patient per year.[16] One research team estimates the cost of production at U.S. $5,676 per year.[17]

Internationally, while cystic fibrosis groups protested Vertex's pricing, citing the company's "staggering profits of $9 billion in 2022from CF product revenues,"[18] patient advocates in Canada instead attacked the PMPRB's proposed

Guidelines, which Vertex initially cited as a reason not to bring the drug to Canada. This claim was as silly as companies claiming they would abandon the U.S. market if the U.S. used the Inflation Reduction Act to lower drug prices south of the border. Of course, Vertex would market Trikafta in Canada, and they did, but not until they had garnered headlines knocking the PMPRB as a threat to vulnerable patients. Yet instead of calling the company's bluff, advocacy groups joined the attacks on the PMPRB, even intervening to support the industry's case against the PMPRB in Quebec Superior Court and the Quebec Court of Appeal.[19]

Every province and territory in Canada now funds Trikafta, as they should. But is Canada paying a "reasonable" price? I don't know if Canadians are paying more than other countries. But the advocacy of patient groups here surely undermined the ability of provinces to bargain for a fair price. And the latest CIHI report states that Trikafta was the top contributor to increased spending by public drug programs in 2022. [20] At $225 million, spending on Trikafta accounted for roughly 25% of the increase in public drug spending last year.

Towards improved PMPRB engagement with the Public

If the PMPRB wants to engage with members of the public who are concerned about drug prices, the agency needs to revamp its consultation process to recognize that we are not all on an equal footing.

- Require all participants involved in public engagement to declare their financial and personal relationships to the pharmaceutical industry and exclude submission from groups that fail to reveal their conflicts.
- Arrange regular meetings with public interest groups independent of the industry and industry-funded groups.
- Provide funds to groups representing the public interest that do not receive industry funds if they intend to intervene on PMPRB policy.
- Take steps to ensure that any advisory committees, round tables, and meetings are publicized to public interest groups independent of pharma and that the PMPRB welcomes the involvement of these groups.

Towards a PMPRB in the public interest

The PMPRB must assert that its mission is not to "make the (industry) stakeholders happy," and act accordingly. To reinforce the agency's mandate -- to cap excessive prices in the interests of protecting the public health -- PMPRB board members must be independent of the industry. PMPRB staff should be barred from revolving door employment with pharma for 3 years.

Notes and References

[1] I am affiliated with Dalhousie University's departments of Bioethics and Political Science, and with the drug policy organization PharmedOut at Georgetown University in DC. I am also a founding member of the research and advocacy organization Independent Voices for Safe and Effective Drugs, and a board member of the advocacy organization Nova Scotia Health Coalition, however, this submission was prepared independent of these organizations.
[2] Full CV at Department of Bioethics, Dalhousie University.
[3] The IVSED website (ivsed.org) includes a page on the PMPRB and links to our interventions, including a letter to Prime Minister Trudeau, May 10, 2019, an initial response to the PMPRB proposals (April 24, 2020) and a submission to the Dec. 2022 consultation. Also included, our press release on the appointment of Thomas Digby, in February 2023.
[4] Sharfstein, Joshua M. Banishing "Stakeholders". *The Milbank Quarterly* 2016; 94(3):476-479.
[5] Marks, Jonathan H. 2019. *The Perils of Partnership: Industry influence, institutional integrity and public health.* New York: Oxford University Press.
[6] Das S, Ungoed-Thomas J. Revealed: Drug firms funding U.K. patient groups that lobby for NHS approval of medicines. *The Guardian*. July 22, 2023.
[7] McCoy et al. Conflicts of interest for Patient-Advocacy Organizations. *NEJM* 2017;366:880-885.
[8] Bhat S, Ross JS, Ramachandran R. Medical product industry ties to patient advocacy organizations' executive leadership. JAMA Internal Medicine. August 21, 2023. doi: https://doi.org/10.1001/jamainternmed.2023.2842
[9] Lexchin J. Donations made and received: A study of disclosure practices of pharmaceutical companies and patient groups in Canada. *International Journal of Health Policy and Management.* 2022; 11: 2046-2053.
[10] Elliott C. The Purchased Patient Advocate. *Hastings Center Report*. 2018; March-April.
[11] Mitchell D. Letter from P4ADNow Founder David Mitchell on Drug Price Reforms. Patients for Affordable Drugs Now. Latest News. April 5, 2022.
[12] Batt, S. Competing values, competing claims: Diversity among patient advocates who intervene to shape policies on drugs for rare diseases. HealthcarePapers. 2023; 21(1): 52-58.
[13] PMPRB. PMPRB Hearing Panel issues order in Procysbi case. PMPRB Press Release. 2022, November 8.
[14] In April 2021, a coalition of industry-funded patient groups sponsored on-line advertisements in the *Hill Times*, with the message "Stop Changes to PMPRB Regulations." Images and text that implied the proposed regulations were causing delays to life-saving medications. In another campaign, prominent patient advocacy groups including CORD and Best Medicines Coalition, argued that a PMPRB communications plan had maligned them with "false and hurtful statements." In 2020 and 2021, patient advocates attacked the (then) PMPRB executive director and board chair with tweets, accusing them of being untrustworthy and "promoting death and suffering." In our December 2022 submission to a PMPRB consultation, Independent Voices for Safe and Effective Drugs argues that these campaigns frame the PMPRB's role as a body with a "duty of neutrality" to all stakeholders, rather than an agency with a duty to defend the public interest.
[15] Patient View. What 122 Canadian patient groups say about pharma in 2022 – The Patient Perspective, Canadian Edition. Patient View Press Release. May 31, 2023..

[16] Kansteiner, F. Vertex pricing under fire – again—as activists press 4 governments for Trikafta generics. *Fierce Pharma*. Feb 7, 2023.
[17] Guo j, Wang J, Zhang J, Fortunak J, Hill A. Current price versus minimum costs of production for CFTR modulators. *Journal of Cystic Fibrosis*, 2022; 21(5):866-872.
[18] Just Treatment and Vertex Save Us. Letter to Vertex: CF community demands global access to Trikafta. Just Treatment. April 18, 2023.
[19] Merck Canada Inc. c. Procureur général du Canada. 2022 QCCS 4541 (CanLII) <https://canlii.ca/t/jcf42>, consulté le 2023-12-19 and Merck Canada Inc. c. Procureur général du Canada. 2022 QCCA 240 (CanLII), <https://canlii.ca/t/jmjbm>, consulté le 2023-12-19. (The Canadian Cystic Fibrosis Treatment Society, Cystic Fibrosis Canada, and the Canadian Organization for Rare Disorders intervened in both courts to support the industry; see paragraph 90 of 2022 QCCA 240: « Plusieurs groupes, dont des associations de patients, sont intervenus devant la Cour supérieure afin d'appuyer les demandes des sociétés pharmaceutiques. »
[20] Canadian Institute for Health Information. Prescribed Drug spending in Canada, 2023. CIHI. Accessed December 20, 2023.