



**Submission to the Patented Medicine Prices Review Board  
Consultation on new Draft Guidelines**

December 5, 2022\*

From Independent Voices for Safe and Effective Drugs (IVSED)

**Key points**

- IVSED strongly supported efforts to strengthen the guidelines used by the Patented Medicine Prices Review Board and we are disappointed that the strongest reforms have largely been abandoned.
- We also supported the process of consultation undertaken by the PMPRB, which we believe was fair, transparent, and democratic; we are dismayed that parties opposed to the proposed changes used aggressive covert tactics to subvert the process and derail the reforms.
- The PMPRB's price regulation function is essential and should be retained.
- The federal government should put in place a sunshine act that includes patient groups so that industry funding of these groups is visible to the public.
- The government should conduct a thorough study of the accountability rules governing charitable and non-profit organizations that speak on pharmaceutical policy and regulatory issues and take steps to reinforce the line between for-profit companies and non-profit organizations.
- The government should provide public funding to patient and health consumer advocacy groups that adhere to a strict Code of Conduct.

**Who We Are**

Independent Voices for Safe and Effective Drugs was founded in 2016 to represent the full range of patients' interests in the health and pharmaceutical policy arena, including access to safe, effective, and affordable medicines. Our views are based on our experience as patients and caregivers, on many years of direct support and advocacy work with other patients in Canada and beyond, and on our familiarity with the literature on drug development and drug policies. All the patient and public interest health groups we work with maintain financial independence from the pharmaceutical industry. In this respect, unlike many patient advocates, we are free to take positions on drug policy based on research evidence and the lived experience of patients. We also have extensive research experience, including collaborations with colleagues in the health policy, civil society, and academic communities. <https://www.ivsed.org/>

**Members of IVSED**

Wendy Armstrong, Edmonton  
Sharon Batt, Halifax  
Janet Currie, Edmonton  
Colleen Fuller, Vancouver  
Linda Furlini, Montreal  
Terrie Hendrickson, Vancouver  
Erin Little, Port Elgin  
Nancy Olivieri, Toronto

*Submission prepared by Colleen Fuller and Sharon Batt for Independent Voices for Safe and Effective Drugs. Please direct any questions to the authors at [colleenfuller3@me.com](mailto:colleenfuller3@me.com) or [sharon.batt@dal.ca](mailto:sharon.batt@dal.ca).*

## Summary

IVSED supported the proposed 2019 PMPRB Guidelines, as well as the transparent, fair and democratic process undertaken by the Patented Medicines Price Review Board. We were disappointed that Health Canada retreated from earlier commitments to implement the changes in the face of aggressive and questionable tactics employed by the pharmaceutical lobby and the patient groups they fund to oppose the Guidelines. We believe that the PMPRB is vulnerable to ongoing efforts to undermine its mandate to protect the public interest against excessive drug prices.

The decision not to implement the recommended Guidelines leaves Canadians more exposed to excessive and unfair prices for the medicines they need to survive. The rejection of the PMPRB's recommendation to employ a "value-for-money" lens to determine the therapeutic value of drugs in the context of other public health needs disrupts efforts within Canada to align our pricing regimes with those in peer countries. It also endangers efforts to establish a National Pharmacare program that will need to access fairly-priced essential medicines.

Like many others in Canada and internationally, IVSED has concerns that relationships between the pharmaceutical industry and the patient groups they fund take place outside any regulatory framework requiring disclosure of potential conflicts of interest and transparency regarding the terms of funding. We have seen how this relationship has severely hampered efforts to reduce barriers to needed medicines by vulnerable Canadians.

We propose that Health Canada initiate a thorough examination of charitable organizations which lobby on behalf of the pharmaceutical industry and move to develop and implement sunshine laws requiring drug and device manufacturers to disclose how much they provide to each patient advocacy group and under what terms. Finally, we propose that the federal government develop a funding strategy for organizations that represent patient interests but refuse or are denied funding from drug and device manufacturers.

### **I. IVSED's Support for Strengthened Guidelines**

In 2019, we submitted a letter to the Prime Minister outlining our strong support for efforts to strengthen the guidelines used by the Patented Medicine Prices Review Board. We also expressed our concerns that patient groups that receive funding from the pharmaceutical industry were mounting an aggressive campaign to thwart these efforts.

For four years IVSED participated in the extensive consultations on the revised Guidelines that were held with Canadians across the country. Although we didn't believe the draft Guidelines went far enough, we felt the proposed reforms would strengthen the PMPRB's role in protecting Canadian consumers from the excessive costs of patent medicines by introducing new requirements for determining and monitoring patented drug price ceilings.

We particularly welcomed two reforms: the new basket of comparator countries to set drug prices in Canada, and stronger rules that would have allowed the PMPRB to assess value-for-money based on the actual price paid by patients at the cash register, rather than the industry's inflated numbers. We also supported the benchmarking of prices against countries more akin to Canada, requiring information from the pharmaceutical industry about actual prices (including rebates and discounts) paid in Canada, and incorporating a pharmacoeconomic lens to determine the therapeutic value of drugs in the context of other public health needs. We believed that these amendments would lend positive support to plans

for a National Pharmacare program which will need to access essential medicines at fair prices.

Our support also extended to the process of consultation undertaken by the PMPRB, which we believe was fair, transparent, and democratic. The face-to-face consultations we participated in included a broad range of views from across the country and from different sectors, including seniors, those with rare diseases and patients with lived experience not only of disease but also with the real-world struggle of paying for the medicines that they, their children or parents needed to survive.

The previous draft guidelines brought Canada more in line with peer countries (except the US, globally recognized as an outlier among high-income countries for its exceptionally high drug prices). We are disappointed that the strongest reforms have largely been abandoned. We agree with commentators who have attributed the government's pullback to the aggressive opposition from the pharmaceutical industry and the constellation of patient groups they fund.

## **II. Our Concern with Pharma's Aggressive Tactics to Oppose the Guidelines**

Despite the exemplary aspects of the PMPRB's process, the regulations and guidelines that were to come into force January 1, 2020 were postponed multiple times at six-month intervals, then had their most significant changes stripped away. Canadians are now left to wonder how an initiative to make essential drugs affordable to those who need them, ended up being "a commitment to support pharmaceutical companies."<sup>1</sup>

As a group that monitored the process closely for four years and engaged in good faith with many public consultations, we believe the answer is clear: Innovative Medicines Canada (IMC), the lobby group for brand name pharmaceutical companies, opposed both the new regulations and the PMPRB's proposed Guidelines, which would have alleviated the burden of excessively high drug prices on patients and public and private plans. The IMC collaborated with its US counterpart, PhARMA, with member companies, public relations firms, think tanks that promote low taxes and deregulation, and patient advocacy groups that the industry funds, to hijack the discourse with shockingly aggressive tactics. For example:

- The industry offered to spend C\$1B over 10 years to boost Canadian manufacturing and to support access to medicines for rare diseases. In exchange, the government would have to scrap the parts of the guidelines requiring evidence that expensive new drugs provide Canadians value for money<sup>2</sup>;
- Innovative Medicines Canada and its member pharmaceutical companies used the Federal<sup>3</sup> and Quebec<sup>4 5</sup> courts to challenge the guidelines, contributing to delays in the process and weakening the guidelines.
- In the midst of one of the most serious public health crises in the last 100 years, IMC launched a series of initiatives to convince the public and patients that implementing the PMPRB guidelines would slow down the supply of medicines and vaccines. These included:
  - IMC president Pamela Fralick repeating messages such as, "the PMPRB's overriding focus on price control, with inadequate attention paid to the value of innovative

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<sup>1</sup> Crowe, K. After a 5-year fight to lower drug prices, Ottawa's pledge quietly falls apart. [CBC News](#). May 12, 2022/

<sup>2</sup> Martell, A. Pharmaceutical industry offers Ottawa \$1billion to scrap pending drug pricing rules, documents show. [Reuters](#). November 15, 2020.

<sup>3</sup> Innovative Medicines Canada v. Canada (Attorney General). Federal Court [Decision](#). June 29, 2020.

<sup>4</sup> Merck Canada Inc. c. Procureur général du Canada. [Décision](#). Québec Cour Supérieure, 18 décembre, 2020.

<sup>5</sup> Merck Canada Inc. c. Procureur général du Canada. [Décision](#). Québec Cour d'Appel, 18 février, 2022.

new medicines to patients, their families and friends ... is a major part of the problem.”<sup>6</sup>

- An IMC Instagram ad in March 2022 asking members of the public to sign a letter to their MP stating that “I recently learned that Health Canada will be implementing new rules ... which will put my access to innovative diagnostics, treatments and vaccines at risk.”<sup>7</sup>
- A press release, issued March 31, 2022, which states that, “IMC continues to be concerned that the proposed amendments to the Patented Medicines Regulations due to come into force on July 1, 2022, will significantly limit access to life-saving medicines and vaccines for Canadians, including those for rare diseases.”<sup>8</sup>

### III. Evidence of Collaboration between Industry and Patient Advocacy Groups

Innovative Medicines Canada (IMC) and many of its member companies appear to have contributed to an equally aggressive and unrestrained campaign by patient groups that receive pharmaceutical industry funding. For example:

- Three patients’ organizations intervened during the court proceedings to make claims in support of the industry. The Canadian Organization for Rare Disorders (CORD) intervened in the Federal Court case, the Quebec Superior Court case, and the Quebec Court of Appeal; the Canadian Cystic Fibrosis Treatment Society and Cystic Fibrosis Canada both intervened in the two Quebec cases.
- Thirteen patient groups identified as “Protect Our Access” ran a series of slick, fear-mongering ads in the *Hill Times* with the message “Stop Changes to PMPRB Regulations,” featuring images of desperate-looking patients, who, according to captions “wait for a vaccine” and “wait for life-saving medicines.” Despite the extensive cross-Canada consultations including patients, and the presence of three industry-funded patient advocates on a PMPRB steering committee, the coalition stated in a press release that patients were “not considered” in PMPRB consultations.<sup>9</sup>
- A barrage of tweets personally attacked the Executive Director and Chair of the PMPRB, including accusations that they were “promoting death and suffering” and “cannot be trusted.” Many of these tweets referred to an internal email obtained through access to information, in which staff members discussed a communications strategy to address their concerns about a disinformation campaign. The furor over the PMPRB’s internal emails gained substantial traction in op-eds, news stories, and even a supporting report by Donald Savoie, a prominent scholar in governance and administration.
- The Savoie report was commissioned by the Canadian Organization for Rare Disorders, an organization with funding from IMC and several dozen pharmaceutical companies. CORD has consistently opposed the PMPRB guidelines.<sup>10</sup> Professor Savoie argued that the PMPRB has a “duty of neutrality” to “ensure not only a level

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<sup>6</sup> Fralick, P. Canada needs to prioritize timely access to life-saving new treatments. [IMC advertising feature](#), *The Globe and Mail* November 14, 2022.

<sup>7</sup> IMC “There is never a good time to limit access to life-saving vaccines and medicines.” Instagram. March 20, 2022.

<sup>8</sup> Innovative Medicines Canada. “PMPRB continues to ignore the value of innovative medicines to Canadians.” [IMC Press Release](#), March 31, 2022.

<sup>9</sup> Protect Our Access. “Health charities and patient groups join together to protect access to breakthrough medical treatments in Canada.” [News Release](#). October 19, 2020.

<sup>10</sup> Savoie, D.J. Report of Donald J. Savoie on Machinery of Government Issues with respect to the Patented Medicine Prices Review Board. [CORD](#). June 7, 2021.

playing field but also to gain the confidence of all stakeholders.” This analysis obscures the fact that the PMPRB’s mandate is to *protect the public interest against excessive prices*. In a more insightful discussion of a regulator’s role, Jonathan Marks, a lawyer and bioethicist who has extensively analyzed the relationship between government and the private sector in public health, argues that the relationship between public health agencies and corporations that market products such as cigarettes, unhealthy foods, and pharmaceuticals require consumer protection agencies to act in ways that must sometimes be adversarial. This willingness to engage in struggle is not a form of disrespect but simply recognizes that private companies have a legal mandate to maximize profits to shareholders, a requirement at odds with public health goals.<sup>11</sup> Contrary to Donald Savoie’s depiction of the industry and industry-funded organizations as stakeholders to be dealt with on a level playing field, Marks’s analysis recognizes the playing field as profoundly unequal. He emphasizes the need for public interest agencies to *actively defend* the public against the well-honed and often predatory profit-maximizing strategies of multinational corporations.

- For these reasons, the campaign to expose the PMPRB’s communications strategy and staff members’ internal discussion of excessively high drug prices has the hallmarks of a manufactured controversy, akin to “gotcha journalism,”<sup>12</sup> aimed at smearing the PMPRB leadership, rather than grappling with the very real problem of high drug prices and respecting the PMPRB’s regulatory duty to defend the public interest.
- Following one of the announced delays in the implementation of the guidelines, in January 2021, Global Public Affairs, a communications company whose website boasts that it represents “the largest corporate sector organizations in the country,” held a webinar for stakeholders that reviewed the PMPRB Guideline process and significant events, such as the delays and the litigation in Federal and Quebec courts. The presentation concluded by urging stakeholders to “get involved” by submitting to the new round of consultations, due February 15, 2021. The final slide announced, “Stakeholder Voices are Having an Impact, your continued engagement on these consultations is crucial.” It listed five patient groups and the names of their campaigns, all of which opposed the PMPRB guidelines: Protect Our Access, CORD, CF Get Loud, the Canadian Association of PNH Patients, and the GI Society of Canada. The presentation appeared to be a primer for patient groups working with the industry to derail the guidelines.

#### **IV. Industry Pressure Undermined the Democratic Process and Killed the Important “Value-for-Money” Assessment in Relation to Excessive Price**

The result of these tactics employed by the industry and the patient groups it funds – including behind the scenes lobbying by both IMC and PhARMA in the US – not only threaten the ability of Canadians to secure access to needed drugs but also undermine the democratic and open process that both the PMPRB and Health Canada were committed to upholding.<sup>13</sup>

Patient organisations that reject industry funding and which brought more independent analyses and perspectives to the consultation process were effectively sidelined

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<sup>11</sup> Marks, J. H. *The Perils of Partnership: Industry Influence, Institutional Integrity, and Public Health*. Oxford, 2029.

<sup>12</sup> Farr, M. The gotcha question is all about reporters doing a star turn. It’s rudeness journalism. [The Guardian](#). May 6, 2022.

<sup>13</sup> Crowe, K. U.S. Pharma’s fight to prevent lower Canadian drug prices. [CBC News](#). February 9, 2019.

in much of the national news coverage about the impact the proposed Guidelines would have on access to medicines. Unfortunately, it also appears their concerns fell on deaf ears at Health Canada, which chose to bend to industry pressure and scrap many of the reforms that would have strengthened Canada's ability to not only protect patients from price gouging, but also enable the PMPRB to utilize tools common in many of our peer countries, including the application of a "value-for-money" or pharmaco-economic framework to its assessments.

An assessment of pharmaco-economic value (PV) was an important new feature of the PMPRB regulations, designed to provide the patient population with the most health benefit within a limited health budget. The PV would have allowed the PMPRB to consider the impact (opportunity cost) of excessively priced drugs across the system, using the standard measure of the Quality-Adjusted-Life-Year (QALY). As the PMPRB noted, however, pharmaceutical manufacturers were "fundamentally opposed to the introduction of PV as a factor...in determining what constitutes an excessive price".<sup>14</sup> Some rare disease groups were also opposed, arguing that these thresholds were "arbitrary and unreasonable."<sup>15</sup> However, for Canadians, this would have been a valuable addition to the PMPRB's powers. The clinical benefit of new drugs is often ambiguous or unknown, which has allowed companies and industry-funded patient groups to press for coverage of very expensive drugs that turn out to have limited clinical value and sometimes significant clinical harm. Unfortunately, in response to industry opposition, this framework has been completely abandoned.

Based on the above, we make four recommendations for action.

## **V. Recommendations**

### **1. Preserve the PMPRB's price regulator functions**

Following the enactment of the watered-down PMPRB regulations, some parties have suggested that the agency should be scrapped.<sup>16</sup> We disagree. Canada needs a drug price research and regulation body that is positioned to serve the public interest on high drug prices. Any changes to the PMPRB mandate should be aimed at strengthening its ability to counter misleading drug promotion and excessive drug pricing. If the proposed Canada Drug Agency is to consolidate the functions of the various drug regulatory agencies, it must include these powers.

### **2. Create a federal sunshine act that includes patient groups**

Patient advocacy plays an important role in the public policy arena in Canada and internationally. Advocacy organizations can amplify voices that want to -- and should be -- part of any discussion about how well or poorly the health system meets the needs of patients who rely on access to high quality services. Patient voices also can provide vital information to the public and to policymakers about how well or poorly medicines and devices work in the real world. Patients and consumers can inform the public and policymakers about lived experiences which either support or challenge evidence about issues ranging from safety and efficacy to fairness and equity.

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<sup>14</sup> Patented Medicine Prices Review Board. Backgrounder on June 2020 draft guidelines: Explanation of changes from 2019 draft guidelines. [PMPRB](#). June 19, 2020. P. 10.

<sup>15</sup> Wong-Rieger, D. PMPRB Guideline Consultation Submission. [Canadian Organization for Rare Disorders](#). February 14, 2020.

<sup>16</sup> Skinner B. and Rawson N. We no longer need the federal tribunal that deals with patent medicine prices. [Niagara Falls Review](#). July 14, 2021.

Yet, while patient advocacy organizations (PAOs) can serve a public purpose, in Canada they must rely on personal and private funds to do so. Many patient groups at both national and international levels rely heavily on funding from the pharmaceutical industry, raising concerns about potential and real conflicts of interest, increased risk of harm to patients, the rise of pro-industry bias in the patient advocacy arena, and the undermining or weakening of patient advocacy in areas that are of no or little interest to pharmaceutical manufacturers.<sup>17,18,19</sup> This has led to increased scrutiny internationally of the impact of these financial relationships, and discussions about what changes in the regulatory environment are needed to both restore public confidence in the integrity of patient advocacy and increase transparency.

In 2019 the Ontario government decided not to implement the Health Sector Payment Transparency Act which would have required drug and device makers to disclose their financial relationships with medical associations, individual physicians, and patient advocacy groups. This was an unfortunate decision and moved Canada further away from its peers in Europe, especially in Nordic countries which have acted more positively on commitments to increase transparency. But it does not preclude Health Canada from proposing regulations and guidelines that support full transparency. Even in the United States, there are ongoing efforts to expand the requirements for disclosure in the Affordable Care Act to require pharmaceutical corporations to disclose information about funding of patient groups.

Some companies in Canada, to their credit, do disclose the names of patient groups they support, but as Joel Lexchin has documented, the information is “haphazard, inconsistent and incomplete.”<sup>20</sup> The lack of disclosure by both patient groups and drug manufacturers in Canada has had a negative impact on the ability of researchers, lawmakers, regulators, patients, and the public to fully assess the relationship between patient advocacy and the industry. It is impossible to determine how much money the industry has invested in patient advocacy in Canada and what they receive in return.<sup>21,22</sup>

### **3. To protect patients’ safety and to prevent the industry from using patient groups to advance corporate agendas, initiate a thorough study of the accountability rules governing charitable and non-profit organizations that speak on pharmaceutical policy and pharmaceutical regulatory issues.**

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<sup>17</sup> McCoy M.S. Industry Support of Patient Advocacy Organizations: The Case for an Extension of the Sunshine Act Provisions of the Affordable Care Act. *Am J Public Health*. 2018 Aug;108(8):1026-1030. doi: 10.2105/AJPH.2018.304467. Epub 2018 Jun 21. PMID: 29927655; PMCID: PMC6050862.

<sup>18</sup> Rose S.L. Patient advocacy organizations: institutional conflicts of interest, trust, and trustworthiness. *J Law Med Ethics*. 2013 Fall;41(3):680-7. doi: 10.1111/jlme.12078. PMID: 24088159; PMCID: PMC4107906.

<sup>19</sup> Pashley D., Ozieranski P., Mulinari S. Disclosure of Pharmaceutical Industry Funding of Patient Organisations in Nordic Countries: Can Industry Self-Regulation Deliver on its Transparency Promise? *International Journal of Health Services*. 2022;52(3):347-362. doi:10.1177/00207314221083871

<sup>20</sup> 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(10):2046-2053.

<sup>21</sup> McCoy M.S. Industry Support of Patient Advocacy Organizations: The Case for an Extension of the Sunshine Act Provisions of the Affordable Care Act. Note 17, above.

<sup>22</sup> Lexchin J., Batt S., Goldberg D., Shnier A. National patient groups in Canada and their disclosure of relationships with pharmaceutical companies: a cross-sectional study. *BMJ Open*. 2022 Mar 9;12(3):e055287. Doi: 10.1136/bmjopen-2021-055287.

Most patient advocacy groups operate either as charitable organizations (allowing them to issue tax receipts to donors) or non-profit organizations, which cannot issue tax receipts. Both types of organizations operate within legal constraints, and both must operate on a non-profit basis.<sup>23</sup> These laws are badly in need of an overhaul. Michael Jenkin, a former head of the consumer section of Industry Canada writes:

...compared to Canada, the performance of consumer organizations in other advanced industrialized countries is impressive in terms of the benefits they bring to consumers, and their presence in their national public advocacy environments.

Jenkin outlines the history of cuts in government funding to consumer organizations in Canada from the early 1990s, and adds:

Canadian consumer groups are not helped by the regulatory structure of consumer protection in Canada. Unlike most countries, where consumer protection is managed by one government with a minister in charge, everywhere in Canada it is shared by two jurisdictions (one federal and one provincial) in ways that are neither wholly logical nor clear, and where consumer protection functions may be spread out among a number of departments within the same government.

He concludes:

...all provincial and federal departments and regulatory agencies should be required to support the full range of intervenor or witness costs when conducting regulatory hearings or public consultations including travel, research, and time spent by staff in preparing briefs and attending hearings. After all, private companies have significant incentives to invest considerable sums in lobbying for their interests because a very significant part of their costs are tax deductible. Government needs to level the playing field for consumer interest advocates.<sup>24</sup>

With respect to patient and health advocacy groups, the now-embedded practice of organizations classified as non-profit receiving donations from corporations and industry groups like IMC blurs the boundary between for-profit companies and non-profit organizations. The dangers these collaborations pose to public health policy is clear in the case of the patient group campaigns against the PMPRB. The public, vulnerable patients, and even agencies like the Parliamentary Budget Office, take on face value that organizations with a non-profit designation are acting solely in the public interest. (A report last June by the Parliamentary Budget Office cites the opposition of two industry-funded patient organizations to the PMPRB changes as evidence that “patient advocacy groups” were concerned that the regulations/ guidelines would delay availability in Canada to new drugs available internationally. The report does not examine the merits of this argument or cite the views of groups that supported the guidelines.)<sup>25</sup>

#### **4. Provide public funding to patient and health consumer advocacy groups that adhere to a Code of Conduct.**

Canada once provided public funding to patient and health consumer organizations as part of a commitment to support civil society organizations engaged on public policy issues. The rationale for this funding was that such organizations can perform unique vital functions in a democracy, such as communicating changing

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<sup>23</sup> Government of Canada. What is the difference between a registered charity and a non-profit organization? [Canada Revenue Agency](#). Web page visited December 4, 2022.

<sup>24</sup> Jenkin, M. Canada’s Consumer Movement: Where to Now? [OC Magazine](#). March 5, 2020.

<sup>25</sup> Bagnoli P, Busby C. Canadian Patented Drug Prices: Gauging the change in reference countries. [Parliamentary Budget Office](#). June 14, 2022, page 11.



political concerns to governments.<sup>26</sup> Influencing the Canadian policy system requires resources beyond the capacity of most public interest groups, this analyst explains, particularly when policy issues are subject to well-funded private sector lobbies, as in the case of pharmaceuticals. The legitimacy of civil society groups can be hard to judge, so requirements such as transparency, democratic elections to boards, and a code of conduct are essential.

Public funding of patient and health consumer groups was curtailed in Canada in the early 1990s, with governments (provincial and federal) even encouraging groups to seek funding from the private sector. The lobbies by patient advocacy groups against the PMPRB are only one example of how this funding strategy has failed patients and the public. Researchers have documented the role of industry-funded patient groups contributing to the opioid crisis<sup>27</sup>, to blocking the adoption of biosimilars<sup>28</sup>, and to opposing the withdrawal of dangerous drugs from the market.<sup>29</sup>

We strongly urge the federal government to re-establish a stream of public funding to patient and health advocacy groups. Criteria for eligibility could include a policy that prohibits funding from the pharmaceutical industry, transparency of funding sources, a decision-making structure that is democratic and independent from the industry (e.g., staff and board members who are accountable to the relevant patient community and free of industry ties), and a commitment to civil discourse when expressing disagreement with other parties.

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*\*Correction, December 6, 3:45 AST: Our submission to the PMPRB misspells Michael Jenkin's name as Jenkins. We have corrected the error in this text.*

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<sup>26</sup> Pross, P. *Group Politics and Public Policy*. 2<sup>nd</sup> ed. Oxford, 1992.

<sup>27</sup> Rendon J. How nonprofits helped fuel the opioid crisis. [The Chronicle of Philanthropy](#). February 1, 2022.

<sup>28</sup> Mulinari S., Pashley D., Ozieransk P. Advancing international comparison of pharmaceutical industry funding of patient advocacy: focus on Denmark. [Health Policy](#) 2022, 126 (12): 1256-1262.

<sup>29</sup> Vitry A, Nguyen T, Entwistle V, Roughead E. Regulatory withdrawal of medicines marketed with uncertain benefits: the bevacizumab case study. [Journal of Pharmaceutical Policy and Practice](#). 2015;8(1):1-11. Doi: 10.1186/s40545-015-0046-2