




# BEST MEDICINES COALITION: CONFLICTS OF INTEREST, CAUSE FOR CONCERN

Rejoinder to the brief submitted to the HESA Committee on October 18, 2017.

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November 22, 2017



**Acknowledgement:**

The authors receive no funding or other support from the pharmaceutical drug industry, the insurance industry or pharmacy chains. Neither do they aspire to such funding in the future.

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On October 18, Best Medicines Coalition (BMC) presented a brief to HESA on behalf of 25 Canadian patient organizations. In its brief, the group presents “Core Positions” and “Key Principles and Considerations” that BMC members agree should be included in a model of “Pharmacare for All Canadians.”

The Best Medicines Coalition brief does not mention the financial support that both BMC and its member groups receive from the pharmaceutical industry. On its website BMC does acknowledge some industry funding without providing names of funders or amounts given. However, from other sources<sup>1</sup> we know that GlaxoSmithKline provided BMC with 13% of its total funding in 2016 and that AstraZeneca funded it as well.

Many member organizations of BMC also rely to some extent, often to a very great extent, on funding from the pharmaceutical industry. At issue is not the sincerity of these advocates or their ability to provide insights on the difficulties faced by patients. Rather, their dependency on money from the pharmaceutical industry puts them in a position of conflict of interest on the issue of a national public drug plan.

### **Conflicts of Interest Matter**

Dependency on funding from the pharmaceutical industry raises the likelihood that these organizations will endorse positions that favour the industry, even when these positions are not in the interests of patients. We believe this is the case with BMC’s brief and its “Principles and Considerations.”

Coming from a coalition of 25 patient groups that agree on “core positions” and “fundamental principles” the brief may carry significant weight with the HESA Committee. Groups funded by the pharmaceutical industry do not, however, represent the views, experiences, or interests of all patient advocates<sup>2</sup>.

### **How Influence Occurs**

Research on conflict of Interest in medicine shows that pharmaceutical companies use “food, flattery and friendship” to develop long-term relationships with physicians, regulators, patient advocacy organisations and others.<sup>3</sup> In the course of these relationships, industry partners provide a variety of monetary and non-monetary gifts that subtly bias recipients’ understandings of drug policies towards the industry goals. Educational materials highlight the positive effects of drugs and downplay the negative,<sup>4</sup> gifts set up an expectation of reciprocal favours,<sup>5</sup> and fear of losing future funding buys silence if a recipient of industry largesse is unsettled by a sponsor’s high prices or questionable actions.<sup>6</sup> Companies can choose to support physicians and advocacy groups that express views compatible with their own, amplifying the voices of one segment of the advocacy community at the expense of those with a different perspective.<sup>7</sup>

### **Member Organizations Funded by the Pharmaceutical Industry**

In Appendix A we provide a list of industry funding for member organizations of BMC gleaned from their websites and from industry sources. Clearly BMC and its member groups are significantly funded by the pharmaceutical industry although the full extent of industry funding is not transparent.

## Evidence of Industry Influence in the Arguments by BMC

We submit that BMC's brief shows evidence of industry influence; that is, the arguments in the BMC brief align with those of the industry, even when research evidence contradicts these arguments. Specifically:

**Over-emphasis on drugs:** BMC's call for a plan that covers drugs for "all chronic, episodic, or acute conditions" needs qualification because for many conditions drugs are overprescribed. The majority of visits to physicians for common health problems end with a prescription,<sup>8</sup> even when the condition can be more appropriately and safely managed by non-pharmacological approaches. Patient groups need to insist on clinical trials that evaluate drugs not only against placebos but against other measures such as the best or other standard treatments available, even if this is an older treatment or does not involve drugs.

**Excessive focus on the "hope factor" of new drugs:** BMC's support for access to a "full array of approved medications ... including more recently approved advancements" suggests a program that would place few limits on which drugs are included for funding, as long as they are "approved." Yet more than 9 out of 10 new drugs approved today show no therapeutic benefits over existing drugs.<sup>9</sup>

Despite this evidence, a 2001 article in the *Globe and Mail* noted that patient groups funded by the pharmaceutical industry had become "far more militant and outspoken about issues like the slow approval of new drugs and reluctance to place new drugs on formularies."<sup>10</sup> Not surprisingly, the industry prefers to fund patient advocacy groups that promote the rapid access to new drugs by accelerated approvals and their addition to formularies.

**Ignoring the dangers of rapid approval of new drugs:** Pressure to approve drugs rapidly has come from both the pharmaceutical industry and from patient organizations funded by the industry, which also look to the industry for information about their new drugs. Under the current system of drug approvals, drugs have been approved that are neither effective nor safe, for the specified indications. Nonetheless, Canada and the US now provide conditional approval to drugs for serious diseases based on preliminary evidence ("surrogate endpoints").

For example in 2008 the FDA approved the anti-cancer drug Avastin (bevacizumab) to treat advanced breast cancer and Health Canada followed suit in 2009, based on evidence that the drug slowed the progression of cancer. In 2011, both the FDA and Health Canada revoked approval of the drug for treating advanced breast cancer because follow-up research found Avastin had no benefit for patient survival and had major safety issues, including hypertension, heart attacks, and gastrointestinal perforation.<sup>11</sup>

The industry's desire to bring drugs to market quickly in order to begin recouping costs of development can lead to unethical practices. For example, the anti-inflammatory Vioxx (rofecoxib), was approved to control arthritis pain but approval was revoked when the drug was found to cause heart attacks and strokes and was no more effective than existing drugs.<sup>12</sup> Yet Merck, the manufacturer of Vioxx, knew about the drug's risk of heart attacks, but did not disclose it to regulators for four years.<sup>13</sup>

**Use of drug industry anti-regulatory discourse:** BMC's call for "timely access" and reference to "access delayed" taps into anti-regulatory discourse in which the pharmaceutical industry claims

drug approvals are excessively slow because of bureaucratic inertia. Research shows, however, that accelerated approvals can result in ineffective or unsafe drugs coming to market.<sup>14</sup>

### **“Codes of Conduct” Do Not Ensure Independence from Funders**

Best Medicines Coalition has a “Code of Conduct Regarding Funding” which applies to the Coalition and all 25 members.<sup>15</sup> BMC leaves it to members to review and accept the Code, to reconfirm commitment to the Code annually, and to confirm to BMC that its members are in compliance. Members are responsible for communicating the policies within their organizations. BMC does not monitor for non-compliance, but rather will respond if a violation is brought to its attention.

Self-monitored ethical codes for physicians have a poor track record. Violations are plentiful for reasons that include lack of aggressive education by the host organization about their content, the absence of monitoring for compliance, and the absence of sanctions for non-compliance.<sup>16</sup> Codes of conduct among patient groups, exhibit similar weaknesses and research indicates they are similarly ineffective.<sup>17 18</sup>

### **Conclusion**

The views expressed in BMC’s brief and its “principles” align with those of the pharmaceutical industry. The very broad drug formulary BMC calls for is a recipe for overprescribing, for the use of ineffective and potentially unsafe drugs, and for excessive cost. A national public drug plan should only include safe and therapeutically effective drugs and requires a method for effective cost control. The ability to include drugs in the formulary, or not, is an effective bargaining tool for governments to obtain drugs at reasonable prices.<sup>19</sup> A plan based on BMC “principles” makes that almost impossible.

### **References**

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<sup>1</sup> GlaxoSmithKline website: <http://ca.gsk.com/en-ca/responsibility/responsibility-reports-and-additional-data/patient-group-funding#20160>;

AstraZeneca website: <https://www.astrazeneca.ca/content/dam/az-ca/Documents/Community-Support-Contributions--2015.pdf>

<sup>2</sup> Sharon Batt. *Health Advocacy, Inc.: How Pharmaceutical Funding Changed the Breast Cancer Movement* (Vancouver: UBC Press, 2017).

For testimony of patients and patient organizations independent of the pharmaceutical industry on the question of a National Pharmacare Plan, see:

- *Independent Voices for Safe and Effective Drugs*: <http://www.ourcommons.ca/Content/Committee/421/HESA/Brief/BR8488763/br-external/IndependentPatientVoicesNetworkOfCanada-e.pdf>;
- *Pharmacare2020* (see Voices): <http://pharmacare2020.ca>;
- *Faces of Pharmacare*: <https://www.facesofpharmacare.ca/all/>

<sup>3</sup> Dana Katz, Arthur Caplan, and Jon Merz, “All Gifts Large and Small: Toward an Understanding of Pharmaceutical Industry Gift-Giving,” *American Journal of Bioethics* 3, 3 (2003), 41.

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- <sup>4</sup> Marcia Angell. "Marketing Masquerading as Education," in *The Truth About the Drug Companies: How they Deceive us and What to Do About It*. (New York: Random House, 2004), 135-155.
- <sup>5</sup> Michael J. Oldani, "Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices," *Medical Anthropology Quarterly* 18 (2004), 325–56.
- <sup>6</sup> Joe Nocera, "How Drug Company 'Benevolence' Silences the Sick" *Bloomberg View*, April 18, 2017. <https://www.bloomberg.com/view/articles/2017-04-18/valeant-drug-company-benevolence-and-the-silence-of-the-sick>
- <sup>7</sup> Daniel Carlat, "Dr. Drug Rep," *New York Times Magazine*, November 25, 2007.
- <sup>8</sup> IMS Brogan, Canadian Disease and Therapeutic Index, 2015. Available at: <http://tinyurl.com/zlh9bzd>
- <sup>9</sup> Donald W. Light and Joel R. Lexchin, "Pharmaceutical Research and Development: What Do We Get for All That Money?" *BMJ*, 345 (2012), e4348.
- <sup>10</sup> André Picard, "Charities 'Thank God' For Drug Firms' Money," *Globe and Mail*, January 4, 2001, A8.
- <sup>11</sup> Andrew Pollack, "FDA Revokes Approval of Avastin For Use as Breast Cancer Drug" *New York Times*, November 18, 2011.
- <sup>12</sup> Jeanne Lenzer. "FDA Advisors Warn: COX2 Inhibitors Increase Risk of Heart Attack and Stroke" *BMJ*, 330 (2005), 440.
- <sup>13</sup> Sarah Boseley. "Drug Giant Ignored Vioxx Heart Risk," *The Guardian*, November 5, 2004. <https://www.theguardian.com/society/2004/nov/05/health.research>
- <sup>14</sup> Joel Lexchin, "Postmarket Safety Warnings for Drugs Approved in Canada Under The Notice Of Compliance With Conditions Policy," *British Journal of Clinical Pharmacology*, 79, 5 (2015), 847-59.
- <sup>15</sup> See "Adoption and Enforcement," *Best Medicines Coalition Code of Conduct Regarding Funding* (2014), 4. <https://bestmedicinescoalition.org/wp-content/uploads/2017/04/BMCCCodeofConductRegardingFunding.pdf>
- <sup>16</sup> Joel Lexchin, "Guidelines on Relationships between Industry and the Medical Profession: A Guide to Salvation?" in *Doctors in Denial: Why Big Pharma and The Canadian Medical Profession Are Too Close for Comfort* (Toronto: James Lorimer & Co., 2017), 149-181.
- <sup>17</sup> Sharon Batt. *Health Advocacy, Inc.: How Pharmaceutical Funding Changed the Breast Cancer Movement* (Vancouver: UBC Press, 2017), 197-200.
- <sup>18</sup> David Hughes and Bryn Williams-Jones, "Coalition Priorité Cancer and the Pharmaceutical Industry in Quebec: Conflicts of Interest in the Reimbursement of Expensive Cancer Drugs?" *Healthcare Policy/Politiques de Santé*, 9, 1 (2013), 52-64, citation p. 61.
- <sup>19</sup> Steve Morgan and Marc-André Gagnon. House of Commons of Canada. Standing Committee on Health. October 19, 2017. Evidence presented on The Development of a National Pharmacare Program. <http://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/meeting-74/evidence>

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**Appendix-A**  
**Pharmaceutical Industry Funding of Selected Member Organizations of BMC**

*Arthritis Consumer Experts:* acknowledges funding by Amgen Canada, AstraZeneca Canada, Celgene, Eli Lilly, Hoffman-La Roche, Merck, Novartis, Pfizer, Sandoz, Sanofi, and UCB Canada. No amounts given.

*Asthma Society of Canada:* 45% of total income from corporate sources of which 15.5% was from GlaxoSmithKline.

*Better Pharmacare Coalition:* acknowledges funding from the pharmaceutical industry but provides no details. However GlaxoSmithKline indicates it provided 18.7% of the organization's total revenue for 2016.

*Brain Tumour Foundation of Canada:* no funders acknowledged on its website but AstraZeneca provided some funding in 2015.

*Canadian Arthritis Patient Alliance:* acknowledges funding from AbbVie Canada, Amgen Canada, Arthritis Alliance of Canada, The Arthritis Society, Canadian Rheumatology Association, Eli Lilly Canada, Hoffman-La Roche, Janssen Canada, Novartis, Ontario Rheumatology Association, Pfizer Canada, and UCB Pharma. No amounts given.

*Canadian Breast Cancer Network:* acknowledges "key funders" include Amgen, AstraZeneca, Novartis, Pfizer, and Roche. No amounts given.

*Canadian Hemophilia Society:* acknowledges donors of \$10,000 or more: Pfizer, Bayer, Biogen, Shire, CSL Behring, NovoNordisk, Octapharma, Hoffmann-la Roche. No precise amounts given.

*Canadian PKU and Allied Disorders Inc:* acknowledges Biomarin provided 46% of total income in 2015. Other funders (2016) include Nutricia Metabolic Nutrition, Amerisource Bergen, Cambrooke Therapeutics, Innovative Medicines Canada. No amounts given.

*Canadian Psoriasis Network:* acknowledges funding from Abbvie, Amgen, Janssen, LePharma, Eli Lilly. No amounts given.

*Canadian Skin Patient Alliance:* acknowledges funding from Abbvie, Aspri Pharma, Celgene, Galderma, GlaxoSmithKline, Innovative Medicines Canada, Janssen, Leo Pharma, Merck, Novartis, Valeant. No amounts given.

*Canadian Society of Intestinal Research:* see its sister group, *Gastrointestinal Society*, below

*Canadian Spondylitis Association:* acknowledges funding from Abbvie, Janssen, Merck, Novartis, UCB. No amounts given but donors are listed in decreasing order of contribution.

*Canadian Treatment Action Council:* acknowledges funding from Abbvie, Gilead, HiiV Healthcare. Pharmaceutical industry funding accounted for 21% of total revenue in 2015/16 and 11.5% in 2016/17. HiiV provided \$37,500 in 2016 (5% of total revenue).

*Crohn's and Colitis Canada:* acknowledges funding from Abbvie, Janssen, Pfizer, Takeda. No amounts given but funding from all corporate sources accounted for 20% of total revenue in 2015/16 and 14% in 2016/17.

*Foundation Fighting Blindness:* acknowledges funding from Alcon, Allergan, Bayer, Novartis. Funding from all corporate sources accounted for 4.4% of total revenue in 2016.

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*Gastrointestinal Society*: acknowledges funding from “corporate and other” sources equaled 78% of total funding in 2016. No breakdown is given although from other sources we know that AstraZeneca and GlaxoSmithKline provided funding.

*Health Coalition of Alberta*: No funding information available.

*Kidney Cancer Canada*: acknowledges funding from AbbVie, Astellas Pharma Canada, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Canada’s Research-Based Pharmaceutical Companies (Rx&D), Celgene Canada, Eli Lilly, Gilead, GlaxoSmithKline, Innomar Strategies, Janssen, Merck, Novartis, Pfizer, Roche, Takeda. No amounts are given. In 2015 GlaxoSmithKline gave \$22,500 representing 2.8% of the organization’s total revenue.

*Lymphoma Foundation Canada*: acknowledges funding from Abbvie, Adjuvantz, Amgen, Celgene, Gilead, Hoffman-La Roche, Janssen, Lundbeck, Novartis, Seattle Genetics, Teva.

*Ovarian Cancer Canada*: no acknowledgement of pharmaceutical industry funding. However AstraZeneca acknowledged it provided funding in 2015. No amount was given. Corporate funding from all sources amounted to 12% of total revenue in 2016/17.

*Parkinson Society Canada (currently named Parkinson Canada)*: acknowledges funding for their clinical guidelines website (<http://www.parkinsonclinicalguidelines.ca/home>) from Abbott, Merck, Novartis, Teva, UCB. Corporate funding from all sources amounted to 13% of total revenue in 2016.

The information in Appendix A was obtained mostly from the websites of the various organizations. Additional information was taken from the websites of GlaxoSmithKline (<http://ca.gsk.com/en-ca/responsibility/responsibility-reports-and-additional-data/patient-group-funding#20160>) and AstraZeneca (<https://www.astrazeneca.ca/content/dam/az-ca/Documents/Community-Support-Contributions--2015.pdf>).