CURRENT ONCOLOGY
A Canadian Cancer Research Journal

EDITORIAL

The politicization of oncology drug funding reviews in Canada

C. Skedgel MDE PhD*† and T. Younis MBBCh‡

An article in this issue by Srikanthan, Gill, and Chan[1] considers the possible "politicization" of cancer drug funding announcements in Canada. Specifically, the authors examine the number of cancer-drug funding announcements in the weeks before a provincial election, hypothesizing that incumbent political parties might use such announcements for political gain. Reassuringly, they found no evidence of such behaviour. However, the fact that they thought it worthwhile to look for such evidence suggests that concerns about the inappropriate influence not only of politicians, but also the pharmaceutical industry, patient advocacy groups, and even the media in the drug approval process are pervasive. Such concerns are supported by a recent study that reported a statistically anomalous number of provinces announcing the funding of cholinesterase inhibitors in the days immediately preceding a provincial election[2]. Other studies show that greater media attention to some drugs appears also to be associated with more rapid review and approval processes and that the coverage might have influenced the decisions[3,4]. There is also evidence of potential conflicts of interest between pharmaceutical companies and patient advocacy groups[5,6] and anecdotal concerns about "astroturfing" or organized marketing campaigns disguised as grassroots advocacy[7].

At the root of the concerns is a suspicion that some groups are co-opting the drug review process for their own political, economic, or personal benefit, to the detriment of the larger society. To understand the legitimacy of that suspicion, it is useful to briefly review the purpose and aims of the cancer drug review process in Canada, focusing on the pan-Canadian Oncology Drug Review (pCODR). Currently, pCODR is administered within the Canadian Agency for Drugs and Technologies in Health, alongside the Common Drug Review (CDR). Where pCODR is responsible for cancer drugs, the CDR is responsible for reviewing non-cancer treatments[8,9]. After Health Canada has approved a drug for safety and efficacy[10], the CDR and pCODR both make reimbursement recommendations to provincial and territorial drug plans; however, those recommendations are nonbinding, and each jurisdiction makes its own final reimbursement decision. Notably, many of the provincial decisions are made after strictly nondisclosable price negotiations with the pharmaceutical manufacturer[11].

The stated objective of the pCODR review process is "to bring consistency and clarity to the assessment of cancer drugs." The pCODR deliberative process and recommendations emphasize four key elements: clinical benefit, economic evaluation (value for money), patient-based values, and adoption feasibility[12]. There is, however, no weighting scheme for those criteria and no quantitative threshold that must be met for any single element of the review. The pCODR assessment process also emphasizes transparency in the reporting of all decisions and the evidence on which those decisions were based. A key challenge in that process is that, in many cases, the criteria can be at odds: drugs might be cost-effective, but have a substantial budget impact that limits adoptability; or drugs might have marginal clinical benefit and significant adverse effects, but represent the only treatment available for patients with a rare disease.

To arrive at a final recommendation, the pCODR Expert Review Committee relies on the judgment of a panel of clinical experts, health economists, and patient representatives who consider the evidence and reach a consensus recommendation. That consensus can be to recommend funding, to recommend not funding, or to recommend funding conditional on (most often) a lower drug price[13]. Conflicts are resolved through discussion, without reference to any explicit decision weights; there is no guidance to indicate what constitutes clinical benefit or good value for money. Committee members therefore apply their own implicit weights to arrive at their consensus. A challenge posed by this sort of approach is the maintenance of consistency: it is possible that a different committee, with different members relying on a different set of implicit weights, could reach a different decision about the same drug. To a large degree, pCODR relies on an "institutional memory" to maintain consistency: Have we reviewed similar drugs in the past, and how did we decide then?

Decision frameworks that guide drug funding recommendations often rely on a predetermined set of criteria involving subjective decision rules rather than explicit thresholds. Proponents of this sort of approach argue that some ambiguity, and even opacity, in the review process is necessary in the face of the inherent complexities of priority-setting, particularly in emotive areas such as cancer care[11,14,15]. Part of the argument is that cancer, more so than many other diseases, has a strong political component that must be recognized and accommodated[11,13]. Indeed, there are precedents in oncology in which health care policymakers at the provincial level have chosen to override recommendations set forward by drug funding review committees. In that sense, a political element has been designed into the process: it is a feature, not a bug[11].

Correspondence to: Chris Skedgel, Norwich Medical School, University of East Anglia, Norwich NR4 7TJ U.K.
E-mail: c.skedgel@uea.ac.uk ■ **DOI:** http://dx.doi.org/10.3747/co.23.3126

In many ways, however, it is the possibility of recommendations based on political rather than clinical or economic factors that drives public suspicion and distrust. Political involvement in priority-setting implies a proverbial "thumb on the scale," and suggests that drug funding decisions are being made on the basis of factors outside those considered important in the review—particularly the characteristics of the *patient* rather than the *drug*. Such political involvement would seem most often to be detrimental to marginalized or otherwise "less worthy" groups and diseases in society. For example, Hoffman-Goetz and MacDonald[16] observed that the coverage of lung cancer in Canadian women's magazines is much lower than coverage of breast cancer, and disproportionately lower than its contribution to women's cancer mortality. Conversely, coverage of breast cancer is much higher than its relative contribution to women's cancer mortality. The relatively lower profile of lung cancer relative to breast cancer might be driven in part by the perception that lung cancer is a self-inflicted illness because of smoking habits. In contrast, breast cancer has a large and well-organized survivorship network and is perceived as affecting otherwise healthy women[3].

In that context, it is difficult to accept that political involvement in priority-setting is likely to be advantageous to marginalized groups. Rather, there would seem to be substantial political advantage associated with being seen to favour higher-profile causes. More broadly, political involvement in the cancer drug review process implies that other disease areas could be marginalized relative to cancer[17]. Indeed, critics argue that ambiguous decision rules can be exploited to the advantage of special-interest groups or, just as damagingly, can be *perceived by the public* as being exploited by those groups[18,19]. Such a perception can lead to a breakdown in the implicit social contract by which individuals with lesser need are willing to stand aside for those deemed to have greater need, on the presumption that others will stand aside for them when they have greater need. If the public does not trust the process by which need and priority are determined, they are less willing to stand aside for others, and the system begins to break down[20].

The pCODR undoubtedly provides a uniform and consistent review process for oncology drugs that critically examines clinical benefit, economic value, adoption feasibility, and patient values. However, the ultimate *objective* of the assessment is not clearly defined in terms of maximizing health outcomes within a constrained budget[17], restraining growth in drug expenditures, facilitating greater and more timely access to innovative cancer drugs, or addressing aspects of equity such as unmet needs and patient values. It is indeed likely that the final objective comprises a bit of them all, even though many of the objectives can be in conflict. For example, it is difficult to address unmet needs while also seeking to restrain spending on drugs. In that sense, it is not just the process but the objective itself that is politicized, as decision-makers try to promote and balance outcomes that are unstated and, to varying degrees, mutually incompatible.

As Hoch *et al.*[11] observe, the current pCODR review process was designed by the provinces to exist outside of, but in parallel to, the CDR, strongly suggesting that it was at least initially intended to serve a distinct and implicitly political purpose. Indeed, as McDonald *et al.*[17] conclude, there is no *economic* rationale for a separate cancer drug review process alongside the CDR. Given that Hoch and Sabharwal[13] are correct in observing that cancer is a politically charged issue, a political purpose is therefore not unexpected. Furthermore, those authors note that pCODR makes only recommendations; the final funding decision is the responsibility of political decision-makers at the provincial level, and therefore a political element in the final decisions is inevitable. In that sense, the public's suspicions of creeping political influence over the cancer drug review process is inaccurate because the current process—that is, pCODR—has had a strong political element from its inception. In the absence of the counterfactual, we might never know how such political involvement has affected the fair and efficient allocation of resources in cancer, and whether, if present, it has caused more harm than good.

CONFLICT OF INTEREST DISCLOSURES

CS has served as health economics reviewer for the pan-Canadian Oncology Drug Review (pCODR), and TY has served as a member of the pCODR's Expert Review Committee. The views presented here are of the authors and not those of either pCODR or the Canadian Agency for Drugs and Technologies in Health.

AUTHOR AFFILIATIONS

*Health Economics Group, Norwich Medical School, University of East Anglia, Norwich, U.K.; †School of Pharmacy, Dalhousie University, Halifax, NS; ‡Department of Medicine of Dalhousie University, at the QEII Health Sciences Centre, Halifax, NS.

REFERENCES

1. Srikanthan A, Gill SS, Chan KKW. Provincial elections and timing of cancer drug funding. *Curr Oncol* 2016;23:154-63.
2. Gill SS, Gupta N, Bell CM, Rochon PA, Austin PC, Laupacis A. The timing of drug funding announcements relative to elections: a case study involving dementia medications. *PLoS One* 2013;8:e56921.
3. Booth CM, Dranitsaris G, Gainford MC, *et al.* External influences and priority-setting for anti-cancer agents: a case study of media coverage in adjuvant trastuzumab for breast cancer. *BMC Cancer* 2007;7:110.
4. Abelson J, Collins PA. Media hyping and the "Herceptin access story": an analysis of Canadian and UK newspaper coverage. *Healthc Policy* 2009;4:e113–28.
5. Hughes D, Williams-Jones B. Coalition Priorité Cancer and the pharmaceutical industry in Quebec: conflicts of interest in the reimbursement of expensive cancer drugs? *Healthc Policy* 2013;9:52–64.
6. Rothman SM, Raveis VH, Friedman A, Rothman DJ. Health advocacy organizations and the pharmaceutical industry: an analysis of disclosure practices. *Am J Public Health* 2011;101:602–9.
7. Marshall J, Aldhous P. Patient groups special: Swallowing the best advice? *New Sci* 2006;192:18–22. [Available online at: https://www.newscientist.com/article/mg19225755-100-patient-groups-special-swallowing-the-best-advice/ (subscription required); cited 27 March 2016]
8. Canadian Agency for Drugs and Technologies in Health (CADTH). *Procedure for the CADTH Common Drug Review.* Ottawa, ON: CADTH; 2014. [Available online at: http://www.cadth.ca/media/cdr/process/CDR_Procedure.pdf; cited 19 April 2015]

9. Canadian Agency for Drugs and Technologies in Health (CADTH). About the pan-Canadian Oncology Drug Review (pCODR) [Web page]. Ottawa, ON: CADTH; n.d. [Available at: https://www.cadth.ca/pcodr/about-pcodr; cited 14 April 2016]
10. Health Canada. How Drugs Are Reviewed in Canada [Web page]. 2015 [Available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php; cited 19 April 2016]
11. Hoch JS, Beca J, Sabharwal M, Livingstone SW, Fields AL. Does it matter whether Canada's separate health technology assessment process for cancer drugs has an economic rationale? *Pharmacoeconomics* 2015;33:879–82.
12. Canadian Agency for Drugs and Technologies in Health (CADTH). Guiding Principles [Web page]. Ottawa, ON: CADTH; n.d. [Available at: https://www.cadth.ca/pcodr/guiding-principles; cited 29 March 2016]
13. Hoch JS, Sabharwal M. Informing Canada's cancer drug funding decisions with scientific evidence and patient perspectives: the pan-Canadian Oncology Drug Review. *Curr Oncol* 2013;20:121–4.
14. Mechanic D. Dilemmas in rationing health care services: the case for implicit rationing. *BMJ* 1995;310:1655–9.
15. Hunter DJ. Rationing healthcare: the appeal of muddling through elegantly. *Healthc Pap* 2001;2:31–7,69–75.
16. Hoffman-Goetz L, MacDonald M. Cancer coverage in mass-circulating Canadian women's magazines. *Can J Public Health* 1999;90:55–9.
17. McDonald H, Charles C, Elit L, Gafni A. Is there an economic rationale for cancer drugs to have a separate reimbursement review process for resource allocation purposes? *Pharmacoeconomics* 2015;33:235–41.
18. Doyal L. The rationing debate. Rationing within the NHS should be explicit. The case for. *BMJ* 1997;314:1114–18.
19. Devlin N, Appleby J, Parkin D. Patients' views of explicit rationing: what are the implications for health service decision-making? *J Health Serv Res Policy* 2003;8:183–6.
20. Broqvist M, Garpenby P. To accept, or not to accept, that is the question: citizen reactions to rationing. *Health Expect* 2014;17:82–92.