

Concepts of bias and appointments to the Governing Council of the Canadian Institutes of Health Research

Elaine Gibson LLM

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In October 2009, the academic health research community and the pharmaceutical industry were brought closer together with the appointment of Dr. Bernard Prigent, vice-president of Pfizer Canada, to the Governing Council of the Canadian Institutes of Health Research (CIHR). This bridging of the two worlds has stirred up considerable debate before the House of Commons Standing Committee on Health,^{1,2} in letters to *CMAJ*³ and in an online petition that garnered more than 4400 signatures.⁴

There are at least two distinct and vocal camps in the debate: those categorically in favour (including the federal minister of health and the president of CIHR) and those opposed to the appointment of someone from the pharmaceutical industry (including several senior Canada Research Chairs with a specialization in ethics⁴ and senior persons within CIHR⁵). There are also some who support the appointment of a person with professional ties to the pharmaceutical industry, but not to this particular company (Pfizer) because of its history of ethical and legal violations.⁶

An important precept borrowed from administrative law may aid in illustrating some of the issues in this debate: the concept of reasonable apprehension of bias. When applied to these circumstances, it cuts through the various arguments to suggest the appointment is indefensible. I'll explain why. But first I will briefly summarize the roles of CIHR and its Governing Council, as well as the arguments made thus far.

CIHR is a statutorily created corporate agency of the federal government. Its objective is "to excel ... in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system." The Governing Council oversees the direction and management of CIHR by developing strategic directions, goals and policies, evaluating the agency's overall performance, and approving its budget. CIHR is intended to function at arm's length from government.⁷

The first argument of those in support of the appointment is that the voice of the pharmaceutical industry will be an invaluable enhancement to the ability of CIHR to meet the needs of the Canadian public. It is important that CIHR be seen to be serving Canadian interests in commercialization and economic development, which are indeed parts of the agency's mandate. There may not have been enough attention paid to these matters, and this appointment will help to fill the gap.⁸

Second, Dr. Prigent has great credentials: his qualifications

Key points

- The appointment of Dr. Bernard Prigent to the Governing Council of the Canadian Institutes of Health Research has generated substantial debate in the worlds of health, research, government and ethics.
- Critics of the appointment argue that having someone from the pharmaceutical industry on the council presents an unmanageable conflict of interest.
- An important precept borrowed from administrative law — the concept of reasonable apprehension of bias — may lend focus to ethical considerations in this situation.
- Application of this concept of bias leads to the perspective that Dr. Prigent's appointment is untenable because his links to the pharmaceutical industry, and to Pfizer specifically, are too close.

are strong, and he is highly respected. He has considerable experience in commercialization and in pharmaceutical development. He chairs the Scientific Advisory Committee of Canada's Rx&D Health Research Foundation, an association of research-based patent-holding pharmaceutical companies; he co-chairs the research working group of Montréal InVivo, the life sciences and health technologies cluster of the Montréal metropolitan area; and he serves on a number of national health-related committees. He has been appointed as an individual because of his skills and experience.

Third, Dr. Prigent will be one voice among many at the Governing Council and will not promote his personal agenda or that of his company or the pharmaceutical industry. Moreover, he will be enjoined from doing so by the need to observe the federal Conflict of Interest Act, the Ethical Guidelines for Public Office Holders and the Guidelines for the Political Activities of Public Office Holders. He will be required to remove himself from discussions at Governing Council in which he, his company or the pharmaceutical industry has a vested interest.⁹

Critics, on the other hand, argue that having an active employee of a health-related commercial entity appointed to CIHR's Governing Council presents an unmanageable conflict of interest. The appointee's primary obligation to shareholders

Elaine Gibson is with the Health Law Institute, Dalhousie University, Halifax, NS.

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means that he cannot detach himself from the role of corporate representative, nor act in a disinterested fashion. The fundamental concern is the shaping of the research agenda in favour of the interests of the pharmaceutical industry.¹⁰

Second, it is argued that Dr. Prigent is tainted by the international track record of his employer, Pfizer, insofar as he has not publicly distanced himself from the company's wrongdoing.² If he can be appointed to the Governing Council "as an individual," presumably he can speak out against wrong-

If an outside observer would reasonably suspect undue influence on the part of the appointee by virtue of his or her conflicting obligations, the appointment should not be made.

doing "as an individual." Pfizer recently agreed to a \$2.3 billion settlement of a lawsuit for its misleading advertising, \$1.3 billion of which was in settlement of criminal charges.¹¹ This was the latest in a series of four occasions on which Pfizer admitted to, and paid fines as a result of legal actions against, its unsavoury business practices.⁶

Third, by removing himself from any discussions at Governing Council in which Pfizer, or the pharmaceutical industry, has a vested interest, Dr. Prigent will be absent from virtually all of the discussions in which he might have significant knowledge to convey. The perceived value of his appointment will thus be diminished or lost.¹²

Fourth, the international trend is toward greater distancing between the pharmaceutical industry and the broader research community in response to the unveiling of scandalous practices by the pharmaceutical industry, such as active suppression of negative research results and hiding important safety and effectiveness data. The US National Institutes of Health has strengthened its conflict of interest policy on independence from industry;¹³ it does not have a pharmaceutical representative on its board.

This brief summary of the proponents' and critics' arguments reveals perspectives worlds apart. An issue unexplored thus far in the debate is a concept borrowed from administrative law: the precept of reasonable apprehension of bias.

Administrative law concerns the rules by which public decision-makers — those who derive their powers from statute or from royal prerogative — fulfil their roles.¹⁴ Arguments by the critics have thus far been shaped around the topic of conflict of interest, which focuses on whether one has a pecuniary interest in a particular outcome of a decision. Conflict of interest is a subset of the topics of bias and independence. Thus, even if a direct pecuniary interest is not at play, decisions may be challenged on the basis of apparent bias or lack of independence.

The concept of reasonable apprehension of bias is an inquiry as to what an informed member of the public, one

step removed from the situation, would think of the possibility for inappropriate factors to influence an appointee's decision-making on a given topic. It was developed historically in the context of tribunals and other bodies serving in a judicial or quasi-judicial capacity. However, it has also been determined by the Supreme Court of Canada to apply more broadly to those exercising administrative functions such as selecting among competing applications to construct a pipeline¹⁵ or those performing a policy-making function such as deciding on and ordering decontamination measures.¹⁶ The latter — the development of policy — constitutes the task of the CIHR Governing Council. Different standards apply depending on the type of function being challenged: the requirements "... depend upon the nature and the function of the particular tribunal."¹⁷ The more quasi-judicial the role, the stricter the standard to be applied.¹⁸ Also, the concept of reasonable apprehension of bias is generally applied in administrative law retrospectively to a

decision. In other words, once a decision is made or a tribunal struck to determine a given matter, one of the parties argues that the ultimate decision cannot be viewed as impartial owing to apprehension of bias.

The argument I am making is not that a court challenge to the appointment of Dr. Prigent would likely succeed on a claim of reasonable apprehension of bias. This would be remarkable given that it is an appointment and not a particular decision being challenged, and that this is a policy-making body and therefore not the usual focus of such a claim. Rather, I argue that the concept of reasonable apprehension of bias is of use in directing our thinking to relevant ethical considerations.

To determine whether there is a reasonable apprehension of bias, one should ask "Would a reasonable person, knowing the facts, believe that the member may be influenced by improper considerations to favour one side?"¹⁹ For example, in one case, a zoning decision of a municipal board was nullified because one member of the board owned property in an area that arguably may have experienced an increase in property values because of the decision.²⁰ It matters not whether the person is actually biased or whether he or she is able in practice to detach his or her personal interests from decision-making in a given capacity. The focus shifts from the qualities of the individual to the perceptions of the reasonable outside observer. The test is whether the observer, apprised of the facts, would assess the circumstance to carry the potential of bias based on the decision-maker's particular position. This test was described by Justice de Grandpré of the Supreme Court of Canada (in dissent, but this description of the test has since been adopted by the Supreme Court of Canada²¹):

[T]he apprehension of bias must be a reasonable one, held by reasonable and rightminded people, applying themselves to the question and obtaining thereon the required information. In the words of the Court of Appeal, that test is "what would an informed person, viewing the matter realistically and practically — and having thought the matter through — conclude."²²

The doctrine of reasonable apprehension of bias is useful because it takes attention away from the question of whether, for instance, Dr. Prigent is an upstanding individual, and instead asks what the well-informed public, one step removed, would think of his appointment. Would there be reasonable grounds for concern about the potential for inappropriate influence on the part of Dr. Prigent in his service on the Governing Council based on his corporate ties?

Whether one is just a single voice among many is viewed as irrelevant, because it is assumed that the individual will have had an impact on the decision. And it doesn't matter whether the decision reached was correct or unimpeachable; the potentially corrupting influence poisons the process.

Just as the CIHR is intended to be at arm's length from government influence, so too should it be at arm's length from the pharmaceutical industry in order to remove the reasonable apprehension of bias by the observer. It is vital that trust in our public institutions not be further eroded.

Therein lies the heart of my argument: the public expects decision-makers to be free of undue influence not only from government but also from the corporate sector, in this case the pharmaceutical industry. Failure to respect this expectation undermines societal trust that is so vital to building and preserving confidence in public institutions.

In appointments to boards, there is latitude for the need to include individuals with expertise in a particular sector. It would be inappropriate not to take advantage of the skills and knowledge of specialists in a given area. The CIHR Act specifies that the Governor in Council is to consider the appointment of members who reflect a range of relevant backgrounds and disciplines. Indeed, because CIHR has commercialization and economic development as parts of its mandate, the council has had, and continues to have, representation from the commercial sector. However, it may be that the appointment of an individual from the pharmaceutical industry is too close for comfort. More certainly, a person currently employed in the higher echelons of a pharmaceutical company cannot function free of the possible taint of reasonable apprehension of bias.

To illustrate an application of the concept of reasonable apprehension of bias, consider Dr. Prigent's role as a registered lobbyist with the Office of the Commissioner of Lobbying of Canada to lobby various institutions, including CIHR, in the promotion of Pfizer's interests.²³ Dr. Prigent may argue, his supporters may argue, and those responsible for his Order-in-Council appointment may argue that he can change hats from lobbyist to public servant on any given day. However, although this claim may be factually accurate, it doesn't matter. If an outside observer would reasonably suspect undue influence on the part of the appointee by virtue of his or her conflicting obligations, the appointment should not be made. It is the *apprehension* of a potential bias that counts. Justice must not only be done; it must be *seen* to be done. Why wait for a particular decision of a board to be challenged on the basis of reasonable apprehension of bias? In furthering this notion, the US administration is currently removing registered lobbyists from advisory boards.¹³

When all is said and done, alas, the newly constructed bridge between the pharmaceutical industry and CIHR brings the parties far too close for comfort.

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Correspondence to: Elaine Gibson, Associate Director, Health Law Institute, Dalhousie University, 6061 University Ave., Halifax NS B3H 4H9; elaine.gibson@dal.ca