

LETTER.....

Getting a fix on good governance

The Olivieri symposium offers an opportunity to reflect on the Canadian regulatory climate and public governance. Baylis's paper raises a concern about the Canadian bioethics community's collective silence and stewardship regarding the Olivieri case.¹ A similar collective silence greeted the recent McDonald report² on research governance in Canada. The McDonald report assessed the integrity and effectiveness of research governance arrangements and concluded that serious reform was required.

Curiously, although the McDonald report was recently referred to in a *Canadian Medical Association Journal* (CMAJ) editorial as an example of Canadian leadership,³ it has never received an editorial commentary in the CMAJ. Nor has any article in the CMAJ ever addressed the McDonald report. Yet the CMAJ created an ethics editorship and a senior Canadian bioethicist was chosen for the position in light of the growing importance of ethics in public policy.⁴ A chapter of the McDonald report also focused on the mandate of the Canadian Medical Association and the provincial colleges of physicians and surgeons and how research governance issues are part of their ethics responsibilities (McDonald,² section D-3). Nor has the McDonald report been discussed in Canadian law and health journals except by its principal investigator.⁵ One might expect a national study on research governance that raises public concerns to warrant more than occasional references. Unfortunately, the McDonald report is rapidly approaching the status of a footnote. Its concerns included token public representation in research governance; widespread institutional conflict of interest; a regulatory system and culture that favours the research community; a narrow view of ethics that is funnelled through research interests; and agendas that influence the thinking and practices of researchers, research institutions, and research ethics boards (REBs)—the ethics watchdogs.

The McDonald report noted that REBs tend to focus narrowly on consent forms; REBs pay too little attention to benefits and harms for research subjects; researchers consider ethics to be a matter of navigating through the REB; and institutions see ethics as little more than the efficient processing of research proposals (McDonald,² section F). Revelations of REBs violating ethics guidelines at academic centres and teaching hospitals heighten the McDonald report's accountability concerns.⁶ And although federal granting agencies can withhold research funding from academic centres that fail to comply with ethics guidelines, this has not occurred to date.⁷

In light of this regulatory climate, the question should be pressed whether it makes good governance sense to enhance REBs' powers along the self governing institutional lines DuVal proposes in the Olivieri symposium.⁸ His proposal puts more power in local REB hands by extending their watchdog function to oversee contracts with sponsors. Clearly, it is sensible for universities and hospitals to ensure that contracts are in keeping with good ethics and the law. But for local REBs to be the regulatory watchdog raises concerns about conflict of interest. As Health Canada notes: "there may be serious conflict of interest on many different levels: within REBs; between researchers and sponsors; and within research institutions".⁹ Research ethics boards are also steeped in a tradition of secrecy. Transparency is a key feature of good public governance and especially important for watchdog bodies if public trust is to be ensured.¹⁰ An open and independent watchdog that is at arm's length from research institutions would better serve the public good.

Against the backdrop of REB violations and accountability concerns raised by the McDonald report, the question also arises whether increasing the bioethics watchdog function would justify public confidence in the kind of self regulating model of governance adopted by the University of Toronto.¹¹ It has been noted that many bioethics centres, including the University of Toronto, receive corporate funding.¹² Concerns about the ethics of marketing and the marketing of ethics to serve institutional ends extend beyond corporate sponsorship. Universities, hospitals, and staff have become entrepreneurial and are producing, testing, and taking out patents on drugs and medical devices. Canadian research centres also advertise to recruit research subjects through local papers, which note that "protocols have been approved by the research ethics committee".¹³ Given REB violations at academic centres and senior bioethicists' silence over the Olivieri case and the McDonald report, Ferris *et al* may overestimate how much moral rigour and power bioethicists can exercise in their institutions as public watchdogs.¹¹

There is growing media and public interest in governance issues because of major corporate scandals. Concerns about corporate governance mirror issues raised by the McDonald report. How long will it take before the Canadian media broadens its governance lens to include the research regulatory culture? A broader discussion about good governance that is actually beyond the Olivieri case needs to take place. Must we await loss of public patience, or can we take charge of the reform process?

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